Exhibit 17

Page 1

UNITED STATES DISTRICT COURT DISTRICT OF NEW JERSEY

IN RE: JOHNSON &)

JOHNSON TALCUM POWDER)

PRODUCTS MARKETING)

SALES PRACTICES AND) MDL 16-2738

PRODUCT LIABILITY) (FLW)(LHG)

LITIGATION)

THIS DOCUMENT)

PERTAINS TO ALL CASES)

WEDNESDAY, DECEMBER 19, 2018

CONFIDENTIAL - PURSUANT TO PROTECTIVE ORDER

- - -

Videotaped deposition of Laura

Plunkett, Ph.D., DABT, held at the Four

Seasons Hotel, 999 North 2nd Street, St.

Louis, Missouri, commencing at 9:12 a.m., on
the above date, before Carrie A. Campbell,

Registered Diplomate Reporter, Certified

Realtime Reporter, Illinois, California &

Texas Certified Shorthand Reporter, Missouri

& Kansas Certified Court Reporter.

GOLKOW LITIGATION SERVICES 877.370.3377 ph | 917.591.5672 fax deps@golkow.com

Case 3:16-md-02738-MAS-RLS Document 9888-5 Filed 05/29/19 Page 3 of 424 PageID: 65319

Confidential - Pursuant to Protective Order

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2	BEASLEY, ALLEN, CROW, METHVIN,		2 PAGE 3 APPEARANCES 2
3	PORTIS & MILES, P.C. BY: TED MEADOWS		4 EXAMINATIONS
4	Ted.Meadows@BeasleyAllen.com		5 BY MS. BRANSCOME 8
5	RYAN BEATTIE Ryan.Beattie@BeasleyAllen.com		6 BY MS. BOCKUS
3	218 Commerce Street		7 BY MR. LOCKE319
6	Montgomery, Alabama 36104 (334) 269-2343		9 EXHIBITS
7	(334) 209-2343		10 No. Description Page
8	ASHCRAFT & GEREL, LLP		11 1 Notice of Oral and Videotaped 8
9	BY: MICHELLE A. PARFITT mparfitt@ashcraftlaw.com		Deposition of Plaintiffs' Expert 12 and Duces Tecum
	4900 Seminary Road, Suite 650		13 2 Expert Report of Laura M. Plunkett, 13
10	Alexandria, VA 22311 (703) 931-5500		Ph.D., DABT, October 5, 2016
11			14
12	LEVIN, PAPANTONIO, THOMAS, MITCHELL, RAFFERTY & PROCTOR, P.A.		3 Supplemental Expert Report of Laura 13
13	BY: CHRISTOPHER V. TISI		15 M. Plunkett, Ph.D., DABT, August 29, 2018
1.4	ctisi@levinlaw.com		16
14	316 South Baylen Street, Suite 600 Pensacola, Florida 32502		4 Rule 26 Expert Report of Laura M. 13
15	(850) 435-7000		17 Plunkett, Ph.D., DABT, November 16,
16	GOLOMB & HONIK, P.C.		2018
17	BY: RICHARD GOLOMB		18 5 "Systematic Review and 16
18	rgolomb@golombhonik.com 1835 Market Street, Suite 2900		19 Meta-Analysis of the Association
	Philadelphia, Pennsylvania 19103		between Perineal Use of Talc and
19	(215) 278-4449		20 Risk of Ovarian Cancer," Taher, et
20	Counsel for Plaintiffs		al.
21	KIRKLAND & ELLIS LLP		21 6 Printout of Health Canada's risk 17
22	BY: KIMBERLY OLVEY BRANSCOME kimberly.branscome@kirkland.com		22 assessment of talcum powder
	WILLIAM SMITH		23 7 "Ovarian, Fallopian Tube, and 111
23	333 South Hope Street		Primary Peritoneal Cancer
24	Los Angeles, California 90071 (213) 680-8370		24 Prevention (PDQ)-Health
	Counsel for Defendant Johnson &		
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1	VIDEOGRAPHER: We are now on	1	DIRECT EXAMINATION
2	the record.	2	QUESTIONS BY MS. BRANSCOME:
3	My name is Jacob Arndt. I'm a	3	Q. All right. Good morning,
4	videographer for Golkow Litigation	4	Dr. Plunkett. I introduced myself right
5	Services.	5	before we started, but my name is Kimberly
6	Today's date is December 19,	6	Branscome, and I am here on behalf of Johnson
7	2018, and the time is 9:12 a.m.	7	& Johnson.
8	This deposition is being held	8	Is it your understanding today
9	in St. Louis, Missouri, In Re: Johnson	9	that you are giving your deposition for the
10	& Johnson Products Marketing Sales	10	purpose of a Daubert analysis in the MDL
11	Practices, for the United States	11	related to Johnson's baby powder?
12	District Court for the District of	12	A. That's my understanding, yes.
13	New Jersey.	13	(Plunkett Exhibit 1 marked for
14	The deponent is Dr. Laura	14	identification.)
15	Plunkett.	15	QUESTIONS BY MS. BRANSCOME:
16	Will counsel please identify	16	Q. I want to start by handing you
17	themselves?	17	what I will mark as Plunkett Deposition
18	MR. MEADOWS: Ted Meadows for	18	Exhibit 1.
19	plaintiffs.	19	Do you recognize the document
20	MS. PARFITT: Michelle Parfitt	20	that I just handed you?
21	for the plaintiffs.	21	A. Yes.
22	MR. BEATTIE: Ryan Beattie for	22	Q. Okay. Have you seen this
23	plaintiffs.	23	document before?
24	MR. TISI: Chris Tisi for	24	A. Yes.
25	plaintiffs.	25	Q. All right. When was this
	Page 7		Page 9
1	MD COLOMB D' 1 1C 1 1 C		
	MR. GOLOMB: Richard Golomb for	1	document provided to you?
2	plaintiffs.	2	A. Either earlier this this
2	plaintiffs. MR. LOCKE: Tom Locke for the	2 3	A. Either earlier this this week or late last week. I don't recall if it
2 3 4	plaintiffs. MR. LOCKE: Tom Locke for the Personal Care Products Council.	2 3 4	A. Either earlier this this week or late last week. I don't recall if it was Friday or Monday.
2 3 4 5	plaintiffs. MR. LOCKE: Tom Locke for the Personal Care Products Council. MS. TINSLEY: Caroline Tinsley	2 3 4 5	A. Either earlier this this week or late last week. I don't recall if it was Friday or Monday. Q. Okay. For the purposes of the
2 3 4 5 6	plaintiffs. MR. LOCKE: Tom Locke for the Personal Care Products Council. MS. TINSLEY: Caroline Tinsley for PTI Union, LLC, and PTI Royston,	2 3 4 5 6	A. Either earlier this this week or late last week. I don't recall if it was Friday or Monday. Q. Okay. For the purposes of the record, could you just identify what the
2 3 4 5 6 7	plaintiffs. MR. LOCKE: Tom Locke for the Personal Care Products Council. MS. TINSLEY: Caroline Tinsley for PTI Union, LLC, and PTI Royston, LLC.	2 3 4 5 6 7	A. Either earlier this this week or late last week. I don't recall if it was Friday or Monday. Q. Okay. For the purposes of the record, could you just identify what the document is that I just handed you as
2 3 4 5 6 7 8	plaintiffs. MR. LOCKE: Tom Locke for the Personal Care Products Council. MS. TINSLEY: Caroline Tinsley for PTI Union, LLC, and PTI Royston, LLC. MR. SULLIVAN: Ryan Sullivan	2 3 4 5 6 7 8	A. Either earlier this this week or late last week. I don't recall if it was Friday or Monday. Q. Okay. For the purposes of the record, could you just identify what the document is that I just handed you as Plunkett Deposition Exhibit Number 1?
2 3 4 5 6 7 8 9	plaintiffs. MR. LOCKE: Tom Locke for the Personal Care Products Council. MS. TINSLEY: Caroline Tinsley for PTI Union, LLC, and PTI Royston, LLC. MR. SULLIVAN: Ryan Sullivan for Imerys.	2 3 4 5 6 7 8 9	A. Either earlier this this week or late last week. I don't recall if it was Friday or Monday. Q. Okay. For the purposes of the record, could you just identify what the document is that I just handed you as Plunkett Deposition Exhibit Number 1? A. It's a notice of oral and
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2 3 4 5 6 7 8 9 10 11 12 13 14 15	plaintiffs. MR. LOCKE: Tom Locke for the Personal Care Products Council. MS. TINSLEY: Caroline Tinsley for PTI Union, LLC, and PTI Royston, LLC. MR. SULLIVAN: Ryan Sullivan for Imerys. MS. BOCKUS: Jane Bockus for Imerys. MR. SMITH: William Smith for Johnson & Johnson. MS. BRANSCOME: Kimberly Branscome for Johnson & Johnson.	2 3 4 5 6 7 8 9 10 11 12 13 14 15	A. Either earlier this this week or late last week. I don't recall if it was Friday or Monday. Q. Okay. For the purposes of the record, could you just identify what the document is that I just handed you as Plunkett Deposition Exhibit Number 1? A. It's a notice of oral and videotaped deposition for myself, dated I don't see the date, but probably on the very last do you need that or just is that enough of an identification? Q. That's all right. Now, contained within the
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	plaintiffs. MR. LOCKE: Tom Locke for the Personal Care Products Council. MS. TINSLEY: Caroline Tinsley for PTI Union, LLC, and PTI Royston, LLC. MR. SULLIVAN: Ryan Sullivan for Imerys. MS. BOCKUS: Jane Bockus for Imerys. MR. SMITH: William Smith for Johnson & Johnson. MS. BRANSCOME: Kimberly Branscome for Johnson & Johnson. VIDEOGRAPHER: Thank you.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	A. Either earlier this this week or late last week. I don't recall if it was Friday or Monday. Q. Okay. For the purposes of the record, could you just identify what the document is that I just handed you as Plunkett Deposition Exhibit Number 1? A. It's a notice of oral and videotaped deposition for myself, dated I don't see the date, but probably on the very last do you need that or just is that enough of an identification? Q. That's all right. Now, contained within the deposition notice there is a reference to a
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	plaintiffs. MR. LOCKE: Tom Locke for the Personal Care Products Council. MS. TINSLEY: Caroline Tinsley for PTI Union, LLC, and PTI Royston, LLC. MR. SULLIVAN: Ryan Sullivan for Imerys. MS. BOCKUS: Jane Bockus for Imerys. MR. SMITH: William Smith for Johnson & Johnson. MS. BRANSCOME: Kimberly Branscome for Johnson & Johnson. VIDEOGRAPHER: Thank you. The court reporter is Carrie	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	A. Either earlier this this week or late last week. I don't recall if it was Friday or Monday. Q. Okay. For the purposes of the record, could you just identify what the document is that I just handed you as Plunkett Deposition Exhibit Number 1? A. It's a notice of oral and videotaped deposition for myself, dated I don't see the date, but probably on the very last do you need that or just is that enough of an identification? Q. That's all right. Now, contained within the deposition notice there is a reference to a request for materials that are identified in
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	plaintiffs. MR. LOCKE: Tom Locke for the Personal Care Products Council. MS. TINSLEY: Caroline Tinsley for PTI Union, LLC, and PTI Royston, LLC. MR. SULLIVAN: Ryan Sullivan for Imerys. MS. BOCKUS: Jane Bockus for Imerys. MR. SMITH: William Smith for Johnson & Johnson. MS. BRANSCOME: Kimberly Branscome for Johnson & Johnson. VIDEOGRAPHER: Thank you. The court reporter is Carrie Campbell and will now swear in the	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	A. Either earlier this this week or late last week. I don't recall if it was Friday or Monday. Q. Okay. For the purposes of the record, could you just identify what the document is that I just handed you as Plunkett Deposition Exhibit Number 1? A. It's a notice of oral and videotaped deposition for myself, dated I don't see the date, but probably on the very last do you need that or just is that enough of an identification? Q. That's all right. Now, contained within the deposition notice there is a reference to a request for materials that are identified in more detail in Schedule A.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	plaintiffs. MR. LOCKE: Tom Locke for the Personal Care Products Council. MS. TINSLEY: Caroline Tinsley for PTI Union, LLC, and PTI Royston, LLC. MR. SULLIVAN: Ryan Sullivan for Imerys. MS. BOCKUS: Jane Bockus for Imerys. MR. SMITH: William Smith for Johnson & Johnson. MS. BRANSCOME: Kimberly Branscome for Johnson & Johnson. VIDEOGRAPHER: Thank you. The court reporter is Carrie Campbell and will now swear in the witness.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	A. Either earlier this this week or late last week. I don't recall if it was Friday or Monday. Q. Okay. For the purposes of the record, could you just identify what the document is that I just handed you as Plunkett Deposition Exhibit Number 1? A. It's a notice of oral and videotaped deposition for myself, dated I don't see the date, but probably on the very last do you need that or just is that enough of an identification? Q. That's all right. Now, contained within the deposition notice there is a reference to a request for materials that are identified in more detail in Schedule A. Do you see that?
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	plaintiffs. MR. LOCKE: Tom Locke for the Personal Care Products Council. MS. TINSLEY: Caroline Tinsley for PTI Union, LLC, and PTI Royston, LLC. MR. SULLIVAN: Ryan Sullivan for Imerys. MS. BOCKUS: Jane Bockus for Imerys. MR. SMITH: William Smith for Johnson & Johnson. MS. BRANSCOME: Kimberly Branscome for Johnson & Johnson. VIDEOGRAPHER: Thank you. The court reporter is Carrie Campbell and will now swear in the witness. LAURA PLUNKETT, Ph.D., DABT,	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	A. Either earlier this this week or late last week. I don't recall if it was Friday or Monday. Q. Okay. For the purposes of the record, could you just identify what the document is that I just handed you as Plunkett Deposition Exhibit Number 1? A. It's a notice of oral and videotaped deposition for myself, dated I don't see the date, but probably on the very last do you need that or just is that enough of an identification? Q. That's all right. Now, contained within the deposition notice there is a reference to a request for materials that are identified in more detail in Schedule A. Do you see that? A. Yes.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	plaintiffs. MR. LOCKE: Tom Locke for the Personal Care Products Council. MS. TINSLEY: Caroline Tinsley for PTI Union, LLC, and PTI Royston, LLC. MR. SULLIVAN: Ryan Sullivan for Imerys. MS. BOCKUS: Jane Bockus for Imerys. MR. SMITH: William Smith for Johnson & Johnson. MS. BRANSCOME: Kimberly Branscome for Johnson & Johnson. VIDEOGRAPHER: Thank you. The court reporter is Carrie Campbell and will now swear in the witness. LAURA PLUNKETT, Ph.D., DABT, of lawful age, having been first duly sworn	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	A. Either earlier this this week or late last week. I don't recall if it was Friday or Monday. Q. Okay. For the purposes of the record, could you just identify what the document is that I just handed you as Plunkett Deposition Exhibit Number 1? A. It's a notice of oral and videotaped deposition for myself, dated I don't see the date, but probably on the very last do you need that or just is that enough of an identification? Q. That's all right. Now, contained within the deposition notice there is a reference to a request for materials that are identified in more detail in Schedule A. Do you see that? A. Yes. Q. Have you reviewed Schedule A?
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	plaintiffs. MR. LOCKE: Tom Locke for the Personal Care Products Council. MS. TINSLEY: Caroline Tinsley for PTI Union, LLC, and PTI Royston, LLC. MR. SULLIVAN: Ryan Sullivan for Imerys. MS. BOCKUS: Jane Bockus for Imerys. MR. SMITH: William Smith for Johnson & Johnson. MS. BRANSCOME: Kimberly Branscome for Johnson & Johnson. VIDEOGRAPHER: Thank you. The court reporter is Carrie Campbell and will now swear in the witness. LAURA PLUNKETT, Ph.D., DABT, of lawful age, having been first duly sworn to tell the truth, the whole truth and	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. Either earlier this this week or late last week. I don't recall if it was Friday or Monday. Q. Okay. For the purposes of the record, could you just identify what the document is that I just handed you as Plunkett Deposition Exhibit Number 1? A. It's a notice of oral and videotaped deposition for myself, dated I don't see the date, but probably on the very last do you need that or just is that enough of an identification? Q. That's all right. Now, contained within the deposition notice there is a reference to a request for materials that are identified in more detail in Schedule A. Do you see that? A. Yes. Q. Have you reviewed Schedule A? A. Yes.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	plaintiffs. MR. LOCKE: Tom Locke for the Personal Care Products Council. MS. TINSLEY: Caroline Tinsley for PTI Union, LLC, and PTI Royston, LLC. MR. SULLIVAN: Ryan Sullivan for Imerys. MS. BOCKUS: Jane Bockus for Imerys. MR. SMITH: William Smith for Johnson & Johnson. MS. BRANSCOME: Kimberly Branscome for Johnson & Johnson. VIDEOGRAPHER: Thank you. The court reporter is Carrie Campbell and will now swear in the witness. LAURA PLUNKETT, Ph.D., DABT, of lawful age, having been first duly sworn to tell the truth, the whole truth and nothing but the truth, deposes and says on	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	A. Either earlier this this week or late last week. I don't recall if it was Friday or Monday. Q. Okay. For the purposes of the record, could you just identify what the document is that I just handed you as Plunkett Deposition Exhibit Number 1? A. It's a notice of oral and videotaped deposition for myself, dated I don't see the date, but probably on the very last do you need that or just is that enough of an identification? Q. That's all right. Now, contained within the deposition notice there is a reference to a request for materials that are identified in more detail in Schedule A. Do you see that? A. Yes. Q. Have you reviewed Schedule A? A. Yes. Q. Did you bring any documents
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	plaintiffs. MR. LOCKE: Tom Locke for the Personal Care Products Council. MS. TINSLEY: Caroline Tinsley for PTI Union, LLC, and PTI Royston, LLC. MR. SULLIVAN: Ryan Sullivan for Imerys. MS. BOCKUS: Jane Bockus for Imerys. MR. SMITH: William Smith for Johnson & Johnson. MS. BRANSCOME: Kimberly Branscome for Johnson & Johnson. VIDEOGRAPHER: Thank you. The court reporter is Carrie Campbell and will now swear in the witness. LAURA PLUNKETT, Ph.D., DABT, of lawful age, having been first duly sworn to tell the truth, the whole truth and	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. Either earlier this this week or late last week. I don't recall if it was Friday or Monday. Q. Okay. For the purposes of the record, could you just identify what the document is that I just handed you as Plunkett Deposition Exhibit Number 1? A. It's a notice of oral and videotaped deposition for myself, dated I don't see the date, but probably on the very last do you need that or just is that enough of an identification? Q. That's all right. Now, contained within the deposition notice there is a reference to a request for materials that are identified in more detail in Schedule A. Do you see that? A. Yes. Q. Have you reviewed Schedule A? A. Yes.

Page 10 Page 12 1 The only thing that I believe 1 but I'll bill separately for the time I spent 2 that I had to bring that had not already been 2 yesterday right before the deposition and 3 provided was additional billing since the 3 then at the deposition, so... 4 time of my last deposition. Q. What did you do to prepare for 4 5 5 Okay. And is it my your deposition today? 6 A. I reviewed my reports, the 6 understanding that the documentation related to additional billing that you have done 7 three reports that I filed in the litigation. 7 8 since your prior deposition was produced 8 I had a meeting with attorneys on Monday, and 9 yesterday at the deposition in the Forrest 9 then we had a short meeting yesterday evening 10 because some attorneys arrived that were not 10 case? 11 here on Monday. 11 A. That's correct. 12 12 All right. And the information And essentially went through Q. 13 contained in the documents produced at the 13 some of the documents that -- went through 14 Forrest deposition yesterday, do those 14 some of the documents that I had cited in the 15 contain an up-to-date record of the billing 15 report in certain paragraphs, just to refresh 16 that you have submitted for your work in 16 my memory of what they were. So if you want 17 connection with the litigation against 17 me to tell you which paragraphs, I can do Johnson & Johnson? 18 18 that. 19 A. Yes, with the understanding 19 Q. I will in just a moment. Okay. 20 that I haven't submitted a bill for December 20 Want me to repeat that? I'm A. 21 21 vet. sorry. 2.2 22 Q. Okay. How much time have you That's all right. Q. 23 spent working in connection with your 23 Dr. Plunkett, you referenced 24 opinions in the case against Johnson & 24 the fact that you reviewed specific 25 Johnson related to its baby powder in the 25 paragraphs of your expert reports in Page 11 Page 13 1 1 month of December? preparation for today's deposition. 2 So I'm -- on all the cases that 2 Could you identify those 3 I am involved in that are pending, not just 3 paragraphs for me? this deposition? 4 4 And it's helpful to you, we can 5 I'll ask first all cases and 5 go ahead and mark your three expert reports, then we'll narrow it to the deposition. 6 6 if you're referring to all three. 7 7 A. So in all --A. I'm going to refer just to the 8 8 Q. I mean to the MDL, I'm sorry. MDL report because that's what we're here to 9 Okay. So in all cases this 9 talk about. I mean, if you want to talk 10 month, probably eight hours so far, maybe 10 about what I did to get ready for yesterday 11 11 separately or --12 Q. Does that include the time that 12 MR. MEADOWS: Might be helpful 13 you've spent attending deposition? 13 to go ahead and mark them. 14 A. No, that's not including 14 MS. BRANSCOME: Why don't we go 15 yesterday's deposition time. I apologize. I 15 ahead and just mark the three reports, 16 forgot about that. 16 and then we can walk through. 17 Q. And how much of the eight to 17 (Plunkett Exhibits 2, 3 and 4 18 ten hours that you have spent this month 18 marked for identification.) 19 working on these cases against Johnson & 19 QUESTIONS BY MS. BRANSCOME: 20 Johnson, setting aside the time you spent in 20 Q. So, Dr. Plunkett, do you have a 21 deposition yesterday, relate to the MDL 21 copy of your three reports in front of you? 22 specifically? 22 A. Yes, I do. A. So it will probably be 23 Q. Do those contain any markings, 23 24 billed -- it will be one bill for the 24 highlightings or flags? 25 preparation time because the prep overlapped, 25 A. No, they don't.

4 (Pages 10 to 13)

Page 14 Page 16 1 Okay. Do you mind if we mark 1 are also cited in paragraph 39 as well, some 2 your copies as the official records? 2 of those same ones that are... 3 A. No. that's fine. 3 And then in Section 5 of my 4 So we will mark -- well, let's 4 report where I'm talking about exposure, I 5 5 do this in chronological order. So I am looked again at Parmley and Woodruff. I 6 marking as Plunkett Deposition Exhibit 6 looked again at Vetner and Iturrulde and Egli 7 7 Number 2 the expert report of Dr. Plunkett and Newton last night. 8 8 dated October 5, 2016. And the only other thing I 9 Could you confirm, 9 looked at is not cited in this report because 10 Dr. Plunkett, that that's what I marked as 10 it came out after the report was filed, and Deposition Exhibit Number 2? that was -- and I did bring a copy of that. 11 11 12 12 That was the risk assessment that was done in A. Yes, it is. 13 And then we will mark as 13 Canada. Some people refer to it as -- by the 14 first author's last name, Taher, T-a-h-e-r. 14 Deposition Exhibit Number 3 supplemental 15 expert report of Dr. Laura Plunkett dated 15 And I may be pronouncing that wrong, but... 16 August 29, 2018. 16 (Plunkett Exhibit 5 marked for 17 17 Dr. Plunkett, could you confirm identification.) 18 that I marked that as Exhibit Number 3? 18 QUESTIONS BY MS. BRANSCOME: 19 A. Yes, that's correct. 19 Q. All right. And I see that you 20 Q. And then Exhibit Number 4, we 20 brought a copy of that document with you. 21 will mark the expert report dated 21 Just for the purposes of the record, let's 22 November 16, 2018, by Dr. Plunkett that was 22 mark that as Plunkett Deposition Exhibit 23 23 produced in the MDL. Number 5. 24 Could you confirm that I marked 24 Are there any markings, 25 that as Deposition Exhibit Number 4? 25 highlightings or notations on that document? Page 15 Page 17 1 1 Yes, that's correct. A. No. there's not. 2 All right. And so now back to 2 And then the other document I 3 the question of you referenced the fact that 3 looked at that was not cited in the report, you looked at specific paragraphs of your 4 there is a printout from the government of 4 5 5 expert report in preparation for today's Canada website that talks about some б deposition. If you could, using Deposition б statements on tale, and so I printed that out 7 7 Exhibit Number 4, identify which paragraphs as well. This was published at the same time 8 8 you looked at specifically in preparation for that the risk assessment was published. 9 the deposition. 9 (Plunkett Exhibit 6 marked for 10 A. So it wasn't the paragraphs. 10 identification.) There were certain documents in paragraphs, 11 QUESTIONS BY MS. BRANSCOME: 11 12 12 so that's what I was referring to, so... Q. All right. We'll mark that for 13 purposes of the record as Plunkett Deposition 13 So starting in paragraph 38 14 Exhibit Number 6. We might come back to 14 where I'm talking about sort of the timeline 15 those documents. 15 of information about human health hazards and 16 talc dust. So I just went back and refreshed 16 So returning briefly to the on a few of the older papers. 17 deposition notice and the requests in 17 18 Schedule A, the billing information you 18 I looked again at the patent 19 produced yesterday and then we just discussed documents that are cited in the first bullet. 19 20 additional information with respect to that, 20 I looked again at a paper by 21 are there any other documents that you have Eberl, 1948, which is in the last bullet. 21 in your possession that are responsive to 22 22 The patent documents are also there as well. 23 requests identified in Schedule A that have 23 And that -- so that would be 24 24 not been produced? all I pulled in that paragraph. 25 A. I don't believe so, no. 25 I believe that those documents

Page 18 Page 20 1 Everything -- I do believe that there were 1 Q. All right. And then you 2 some objections filed to this, so there's 2 produced a supplemental report earlier this 3 some things that I did not provide based on 3 year, on August 29, 2018, and that's been 4 marked as Deposition Exhibit Number 3, 4 5 5 Some of the things I don't correct? б 6 have, too. I think you asked for -- maybe A. you didn't ask for that. Usually people ask 7 When did you begin work on the 7 Q. 8 for copies of old depositions, and I don't 8 supplemental report that you produced at the 9 keep those. And maybe you didn't ask for 9 end of August in 2018? 10 that, but that's usually a request. 10 A. I want to say -- let's see. I Let me see. 11 want to say sometime in the summer. Maybe as 11 early as May, but I believe May -- May, June 12 Q. Okay. Now, you mentioned that 12 13 you met with attorneys on Monday. And who 13 time frame of 2018. My billing would reflect that, was present at that meeting? 14 14 15 A. So on Monday it was 15 so, again, we can pull my billing. And I 16 Mr. Meadows, sitting here. Ms. Tucker, 16 would have called it preparation of the Mr. Beattie, were at the meeting on Monday. supplemental report in my billing. 17 17 Q. Okay. Why did you choose to Q. All right. And how long did 18 18 that meeting last? 19 draft a supplemental expert report? 19 20 A. Probably six hours, I guess, 20 A. So over the time I had worked six hours with them, and then I also did some 21 21 on different trials here in St. Louis 2.2 other work on my own, but... 22 particularly, additional documents that were 23 Q. Okay. And then you mentioned 23 not cited in my original report became that you had another meeting last night. 24 24 reliance materials based on their 25 Who was present at that 25 presentation at trial. So there were enough Page 19 Page 21 1 meeting? 1 of those that I thought it was important to add to the original report with additional 2 So that was probably about an 2 3 hour, and that would have been Mr. Tisi -- or 3 documents that I had reviewed over time. 4 maybe two hours. Mr. Tisi joined us 4 Since October of 2016 through, 5 5 yesterday afternoon. And Mr. Golomb, too, let's say, the summer of 2018, there were a 6 variety of additional documents that I had --6 I'm sorry. 7 7 O. All right. Okay. Now, looking I had seen. 8 8 at the three reports that you have produced It was also my understanding 9 9 in the litigation involving Johnson's baby that during that time period Johnson & 10 powder, I wanted to get an understanding of 10 Johnson had provided additional documents 11 how those three reports relate to one 11 that weren't provided or available to me in 12 another. 12 2016, so additional discovery that was now 13 13 available to look at. So some of this is a So you have the first report 14 that you produced that was dated October 5, 14 matter of additional evidence that wasn't 2016. I believe that was originally produced 15 15 available when I wrote my initial -- my 16 in the Uhl case: is that correct? 16 initial report. 17 A. I'm not sure the name of the 17 Q. All right. Now when you say 18 first case, but it was in the -- some of the 18 the additional documents became reliance 19 19 materials in trial, what do you mean by that? St. Louis cases, yes. 20 Q. All right. And when did you 20 A. So additional documents that we 21 begin work on that report? 21 refer to in trial that I use to support 22 A. You'd have to look at my 22 opinions that weren't necessarily 23 billing record, which I know was an exhibit specifically cited within the body of my 23 24 to yesterday's deposition. I believe they 24 report or described within the body of my 25 started in 2015. 25 report. They were likely on my larger

Page 22 Page 24 1 reliance list, but they weren't things that 1 ask who the -- who was involved in the 2 were cited. 2 drafting of the report that was produced in 3 In other words, if you look at 3 the MDL? my original report in -- when I say the body, 4 MR. MEADOWS: Hold on just one 4 the paragraphs. I always put a reference 5 5 second. list and then I'll have Bates numbers. So 6 6 Ask the question one more time. during trial, things that were from my larger 7 7 I want to make sure we're not 8 reliance list that weren't specifically 8 venturing into attorney work product 9 discussed in my report became support for 9 realm here. 10 different opinions that -- based on questions 10 QUESTIONS BY MS. BRANSCOME: at trial. 11 11 Q. Dr. Plunkett, do you consider 12 Okay. When you say these were 12 the report that you have issued in the MDL 13 documents that "we" refer to at trial, you're 13 which is identified as Exhibit 4 to be referring to yourself and attorneys 14 14 attorney work product? 15 representing the plaintiffs? 15 MR. MEADOWS: Objection. Don't 16 A. Yes, that's correct. 16 answer that. That calls for a legal 17 Q. Okay. And understanding that 17 conclusion, and at this point I'm the purpose of today's deposition is focused going to instruct you not to answer 18 18 specifically on the MDL, then you produced a 19 19 questions about how the report came 20 report specific to the MDL on November 16, 20 into be. 21 2018, that we've marked as Exhibit 4. 21 MS. BRANSCOME: Are you 2.2 correct? 2.2 instructing her to refuse to answer 23 23 Yes. any questions that involve the A. 24 When did you begin work on the 24 development of her expert report? 25 report that you produced specifically in the MR. MEADOWS: I'm instructing 25 Page 23 Page 25 1 MDL? 1 her not to answer your last question. 2 A. Sometime right after -- I would 2 QUESTIONS BY MS. BRANSCOME: 3 say early fall of 2018, sometime after 3 Q. Are you following your 4 this -- the supplemental report was filed. 4 attorney's instructions, Dr. Plunkett? 5 5 Probably right after that. A. Yes. 6 Q. Okay. So is it fair to say 6 MS. BRANSCOME: At this point I 7 that you began work on your MDL report after 7 would like to go off the record, 8 completing the supplemental expert report 8 9 that has been marked as Exhibit 3? 9 VIDEOGRAPHER: Okay. We are 10 A. Yes, that's correct. 10 going off the record at 9:30 a.m. 11 Okay. Who was involved in the 11 (Off the record at 9:30 a.m.) 12 VIDEOGRAPHER: We are back on drafting of the report that's been identified 12 13 the record at 9:32 a.m. 13 as Exhibit 4? 14 MR. MEADOWS: Objection. Hang 14 **OUESTIONS BY MS. BRANSCOME:** 15 15 on a second. Q. Dr. Plunkett, other than 16 Are you asking about 16 attorneys, if attorneys were involved -- I am 17 communications between attorneys and 17 not asking questions about that -- were there 18 Dr. Plunkett? 18 any individuals who assisted you in preparing 19 QUESTIONS BY MS. BRANSCOME: 19 the report that has been marked as Exhibit 4? 20 20 Q. Dr. Plunkett, none of the A. There was no one that actually 21 questions I will ask you here today are 21 assisted in writing the report. I do -- when intended to elicit information that's I did my literature searches, I had my 22 22 23 protected by the attorney-client privilege. 23 husband help me retrieve articles that I 24 So setting that aside, anything 24 identified for retrieval, but certainly there 25 that you understand to be privileged, I can 25 was no -- he doesn't participate in the

Page 26 Page 28 1 actual review of articles or in drafting of 1 been marked as Exhibits 2, 3 and 4 to each 2 the report. That's all my work. 2 other, what is your -- what is your position 3 Q. Okay. And when you say that 3 with respect to opinions that you have stated 4 4 your husband retrieved articles, was this or language you have used in Exhibits 2 and 3 5 simply -- what information did you provide 5 that may not appear in Exhibit 4? him in order to enable him to retrieve a 6 6 A. I don't think I understand what 7 7 your -- what you mean by my position. Are particular article? 8 A. So we use a service in Houston 8 you asking --9 called Loansome Doc, which is affiliated with 9 MS. PARFITT: And I'll object 10 our local medical library system and also 10 to that question. 11 with the National Library of medicine and NIH THE WITNESS: Are you asking me 11 libraries. So I give him an online search 12 12 to describe -- I mean, I could 13 that I put into a clipboard. He takes that, 13 describe for you the overlap. I mean, makes the request or retrieves -- some of there's not complete overlap. Is that 14 14 15 them will be free, and so he'll actually go 15 what you're asking me or --16 to the websites for the -- and then put them 16 QUESTIONS BY MS. BRANSCOME: 17 into a folder for me. 17 Q. I am. Why don't you take a So he does that physical part shot at it and then I may narrow my question, 18 18 of it through the computer, but he doesn't -but I'm just trying to understand how the 19 19 20 he doesn't do the searches or decide which 20 reports relate to one another. 21 ones to retrieve. I do that. 21 MR. MEADOWS: Objection. 22 Q. Okay. Did you have any 2.2 THE WITNESS: So they relate to discussions with your husband about the 23 each other, I would say, based on 23 substantive content of the report that's 24 24 timing first, because obviously the identified as Exhibit 4? 25 25 first report was two years ago, and Page 27 Page 29 1 A. No. 1 then many more documents. So that's 2 Q. Does he do any evaluation --2 how the 1 and 2 relate -- or Exhibit 2 3 for example, if you were to provide him a 3 and 3 relate to each other. search and it generates multiple documents by 4 4 In the MDL litigation, I was 5 5 a given author, does he identify additional asked to address very specific topics articles that you might want to consider? 6 and things because there's a -- it's a 6 7 7 A. Only -- he has done that, but different -- I don't know all of them, 8 8 only with the streams of letters to the but there's a different set of experts 9 editor. So I ask him always if I'm pulling 9 that work in different litigations. 10 an article. Happens a lot at the New England 10 So my role in the MDL, I 11 Journal of Medicine or some of the other 11 believe, is set out based on this medical journals where there's pretty active 12 12 report, whereas in the original letter to the editor correspondence that 13 reports I may have had -- I did have a 13 14 14 broader role in some of those cases. happens. 15 15 **OUESTIONS BY MS. BRANSCOME:** So I always say to him, "If 16 there's any citation to this through the 16 Q. Okay. Can you describe for me 17 letter to the editor comments, would you 17 your understanding of your role in the MDL? 18 please retrieve those," and so he will do 18 A. It's my understanding that I 19 that search to look for that. 19 have been asked to provide opinions related 20 20 to the -- generally the toxicology of talcum Q. Okay. 21 And I'm not sure that that 21 powder products, including all the individual 22 constituents that make up that product; to 22 happened in any of these articles, but I'm 23 talking my general process that we use. 23 look historically back in time about what was 24 Q. Okay. In terms of the 24 known and when about the toxic effects of 25 relationship of the three reports that have 25 talc and different constituents within talc.

Page 30 Page 32 1 And that was sort of the -- that's been --1 the companies had, in fact, influenced the 2 I consider that sort of the meat of what I've 2 regulators or PCPC? 3 been asked to do. 3 MR. MEADOWS: Objection. 4 THE WITNESS: Not in my -- not 4 But separate from that, another 5 5 part important part of my testimony or things when I first started this process. So I was asked to provide was an overview of the 6 6 that is -- those opinions actually go 7 regulatory process for cosmetics and then the 7 back into my original report. So 8 information that accumulated scientifically, 8 that's not something, I don't believe, 9 how that related to what a company is 9 that was not covered in my original 10 required to do under the regulations in order 10 report or even in my supplemental 11 to provide consumers with appropriate report. I just have different -- some 11 12 information about the safety of the product. 12 additional documents that I have 13 So kind of the regulatory opinions, I guess 13 reviewed. you want to call it, that area. 14 14 **OUESTIONS BY MS. BRANSCOME:** 15 I have sections on that, and I 15 Q. Okav. 16 think you can see that by the different 16 And this is something when I 17 sections in my report where I set out 17 first evaluated the case and first started 18 different general topics. 18 looking at the documents, those are opinions that I had formed based on my review. 19 And then I was also asked to 19 20 address some of the issues related to how the 20 Certainly by the time I drafted 21 information on the safety of talc has been 21 the MDL report, I think if you listened to 22 disseminated publicly and also based on my 2.2 my -- read my trial testimony, you understand 23 review of different internal company 23 I had those opinions at the time I started 24 documents, both from Johnson & Johnson -- or 24 writing this report. 25 from Johnson & Johnson, Imerys, as well as 25 Q. Now, what I'd like to Page 31 Page 33 1 the PCPC, which is the Personal Care Products 1 understand next is, are there -- of the 2 Council, formerly known as the CTFA, to look 2 topics that you just identified that you 3 at those interactions and how those companies 3 understand that you're offering opinions 4 set about to influence the process around the 4 about in the MDL, which, if any, of those 5 5 safety assessment of talc over the years. So topics are in your view new as compared to 6 б different activities that happened with the opinions that you have offered that are 7 7 respect to the ISRTP meetings in the '90s, contained in Exhibits 2 and 3? 8 8 with respect to the NTP process at different MS. PARFITT: Objection. 9 9 points in time. THE WITNESS: So I don't think 10 The CIR process, I think I 10 any of the MDL opinions are new. 11 cover, and I also talk a little bit about 11 QUESTIONS BY MS. BRANSCOME: 12 12 IARC, I believe, as well. Q. Okay. 13 13 So the interactions of the A. I think that they may have --14 industry with the science and then how that 14 they may -- they may cite to additional documents that haven't been cited to in the 15 science ends up getting described within --15 either to regulators or to bodies that are 16 16 first two reports, but I believe there's a 17 reviewing the science related to the 17 significant overlap even on the documents 18 products. 18 that are cited. 19 Q. You mentioned as one of the 19 Q. And you mentioned that your 20 categories that you were asked to opine about 20 role in the MDL is more narrow than the role in the MDL that you were looking to set about 21 21 you've served in other cases. the influence that companies may have exerted 22 22 What topics have you opined 23 23 over the regulatory process or PCPC. about in other cases that you are not 24 When you began that analysis, 24 intending to opine about in the MDL? 25 did you start with the predicate belief that 25 A. So I am not doing general

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causation in the MDL, although I am indeed providing opinions on certain aspects of the cause and effect relationship such as -- you know, I talk about biologic plausibility, underlying knowledge about different toxicities of the compounds over time, but I'm not doing a full causation analysis in my MDL report, and hopefully you see that when you read the report.

2.3

- Q. So as you sit here today, Dr. Plunkett, you are not intending to offer the opinion in the MDL that Johnson's baby powder causes ovarian cancer; is that correct?
- A. Not in those words. I think if you read my report, I talk about the fact that Johnson -- it's my opinion that Johnson's baby powder increases the risk of cancer -- ovarian cancer, which is a different assessment than the way you stated it.
- Q. All right. And it is -- as you sit here today, Dr. Plunkett, it is your understanding that you are not being offered to give a, as you termed it, a general

principles of, first, is there a hazard, is the first step. Is there a hazard that would be relevant to human health.

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Then looking at the data and determining whether that -- that body of data allows you to either quantify risk in some way or to qualitatively shows you that there's a change in risk based on exposure to the product.

So your statement may be as simple as there's an increased risk, or you can take data in a risk assessment and do a quantification such as in a -- a cancer risk assessment based on an animal data set. You might actually calculate a cancer potency factor, for example. Those kinds of things. That's another application of risk assessment. Same basic process but focusing just, for example, on one study.

My human health risk assessment or safety assessment, like the causation analysis, does look across all kinds of data, but my goal was not to analyze the data under the Hill considerations, which is what I would typically do, in order to go through

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causation opinion in the MDL, correct?

A. That's my understanding, yes.

Q. Now, you mentioned that the analysis as to whether a substance increases the risk of a particular outcome is different than a causation analysis.

Can you explain to me what you meant by that?

A. So I discussed this yesterday in my deposition. There's -- there's a process called risk assessment. Sometime -- in the area of consumer products you can also refer to it as safety assessment. And then there's the process of what I call general causation analysis, or full causation analysis.

So even though the types of information that are considered may overlap between those two, the outcome or the statements or the -- the way you go about assessing the information is a bit different.

Q. Explain to me how they're different.

A. So in a risk assessment, the process starts with setting out some basic

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the process of making that final opinion that
indeed baby powder -- exposure to baby powder
through genital application is a cause of
ovarian cancer in women. That's -- to me,
that's a different way to go about thinking
about the question that you have to answer.

And also the -- some of the

And also the -- some of the data that you evaluate is evaluated a bit differently. So, for example, in my increase -- in my issue of increased risk, I use the epidemiology as supporting evidence, but I'm really focused on -- on -- more on the underlying sort of the biologic information that we have that identifies hazard and risk. So looking at the animal data, the exposure potential for the product, and then using that along with what we know with the human experience to characterize risk.

Q. Is there a different level of certainty required to render a causation opinion than to render an opinion that there's an increased risk?

A. I don't know that I'd describe it quite that way but -- because to me it's a

10 (Pages 34 to 37)

Page 38 Page 40 1 different process. I certainly have to be 1 statistical test you would apply, or 2 just as certain about what I say about risk 2 what are you asking? 3 when I do a risk assessment as I do about --3 QUESTIONS BY MS. BRANSCOME: 4 as I do when I'm doing a causation analysis. 4 Q. So understanding that for the 5 I don't -- maybe you mean 5 most part if you're looking at statistical 6 6 something else, so maybe you can -- I mean, significance, you're looking whether the 7 I -- I certainly use the same basic standards 7 confidence interval crosses 1. 8 in my mind, how I weigh evidence to do the 8 Are you following? 9 different processes, but I go about them in a 9 A. Yes, I know that, yeah. 10 little bit different way when I do a risk 10 All right. And so when you're 11 assessment versus -- versus a causation evaluating, though, whether a particular 11 12 analysis. 12 substance, in this case Johnson's baby 13 Q. In your view, does the strength 13 powder, increases the risk of an outcome, 14 14 again, in this case ovarian cancer, would it of the evidence have to be greater in order 15 to determine that an agent causes a disease, 15 be sufficient for you if that increase was 16 for example, than it does simply to say that 16 .01 percent, for example? 17 MR. MEADOWS: Objection. an agent increases the risk of a particular 17 THE WITNESS: That doesn't make 18 18 outcome? 19 MR. MEADOWS: Objection. 19 sense to me, an increase of .01 20 percent, but maybe I can answer it THE WITNESS: I don't think 20 21 I've ever thought about it that way. 21 this way for you based on what you've 22 I would say to you that strength --22 laid out there. 23 the strength of the association is a 23 Certainly when I do a risk consideration under Hill that you 24 24 assessment and I make it -- if I'm 25 apply the epidemiology data mainly, so 25 going to make the conclusion that I Page 39 Page 41 1 that is a different consideration 1 believe that it's my opinion to a 2345678 under causation than you do -- as you 2 reasonable degree of scientific would do it in a risk assessment. 3 certainty that exposure to baby powder But the strength of the 4 in women increases the risk of cancer, 5 evidence, it's still a judgment based I'm having to rely on -- I do rely on on your experience and training as far 6 data that allows me to draw 7 as whether or not there is enough conclusions because either there's a 8 information to be able to say that you statistical significant finding found 9 9 believe that there is -- enough or the -- there's a consistency among 10 information to say that the risk is 10 the pattern of the data that shows 11 increased based on that exposure and 11 there's information that fits together 12 12 consistently. And maybe -- you want those conditions and whatever the 13 13 toxicity profile of that compound is. me to explain what I mean by that? 14 QUESTIONS BY MS. BRANSCOME: 14 No? 15 O. Okay. We'll get into this more 15 Whereas I think what you're 16 a little bit later, but when you say that a 16 asking is when an epidemiologist 17 risk is increased, is there a threshold level 17 applies -- looks at a body of -- in a 18 of increase that you need to see in order to 18 causation analysis looks at a body --19 render an opinion in a court of law that an 19 and I do this, too -- looks at a body 20 20 of epidemiological studies and you agent increases the risk of a particular 21 outcome? 21 weight the studies, obviously you're 22 MR. MEADOWS: Objection. 22 weighting the studies differently THE WITNESS: So I need you to based on whether they have shown 23 23 24 define what you mean by threshold. 24 statistical significance or not, 25 Are you asking me a specific 25 right?

11 (Pages 38 to 41)

Page 42 Page 44 1 1 company evaluating compliance with FDA And it isn't that it's a one to 2 one. If you have one positive and one 2 regulations with respect to cosmetics? 3 3 A. Yes. negative, that isn't how you may 4 Okay. What is your experience 4 decide to finally weight that Q. 5 5 evidence, but certainly you have to with respect to that? 6 consider whether or not what was seen A. So that's -- one of the clients 6 7 7 or reported is showing you something that I currently work for where I am asked to 8 reliable -- or you can make a 8 provide input on advertising, promotion and 9 statement reliably about whether or 9 labeling of some of the products and then 10 also some of the ingredients that are being 10 not that finding was biologically significant. And biologically promoted for use to -- to produce cosmetic 11 11 12 products. So it's the idea of providing that 12 significant would typically be linked to a finding that has statistical 13 advice over my understanding of the 13 regulations what can be said and can't be 14 significance in an epi study unless 14 15 the study was not designed to be able 15 said about certain ingredients. to answer the question properly. 16 This company is involved in 16 17 So -- and I've discussed that a 17 making both ingredients but also some 18 finished products now based on -- it's a little bit yesterday with Mr. Smith on 18 19 the issue of power to detect. So 19 large company that owns a lot of little that's something you do consider in 20 subsidiaries. 20 2.1 21 Q. My question, though, epi. 2.2 Dr. Plunkett, was, have you ever been in a 22 But, yes, statistical 23 decision-making position for a company 23 significance certainly goes into your 24 weight of the evidence there. 24 evaluating compliance with FDA regulations 25 25 with respect to cosmetics? Page 43 Page 45 1 QUESTIONS BY MS. BRANSCOME: 1 MS. PARFITT: Objection. Asked 2 Q. Okay. You talked about you're 2 and answered. intending to offer an opinion with respect to 3 3 THE WITNESS: So that's what what a company is required to do under the 4 I'm saying. They're relying on my 4 5 5 regulations; is that correct? input to make a decision on what will 6 6 A. Yes. go in the materials. 7 7 Q. Okay. What regulations are you QUESTIONS BY MS. BRANSCOME: 8 specifically referring to? 8 Q. Do you have decision-making So cosmetic regulations that 9 9 authority within that company or, as you 10 exist within -- so it's the entire process as 10 described it, are you providing advice and 11 I describe how cosmetic -- what -- are 11 input? 12 12 cosmetics subject to regulation by FDA? Yes. A. I'm providing advice, but the 13 things I'm advising on are the things that 13 What are the types of things that companies 14 have to do before they're marketed, what does 14 happened. So in other words, they don't have the company have to do once the product is on 15 15 anybody in the company that understands the 16 the market, those kinds of things. 16 process of what they can say. So I -- I 17 Q. Have you ever worked directly 17 advise them that you need to remove this 18 for any regulatory agency? 18 language or that this is more appropriate 19 A. No, I have not. 19 language. They make those changes, and then 20 20 And suffice it to say you have that is what is done. 21 never been in a decision-making position 21 So I agree, I'm not an employee 22 within a regulatory agency, correct? 22 of that company. I am a consultant working 23 23 with the company, but it is a little A. That's correct, I have not. 24 Have you ever been in a 24 different than some of the work that I do 25 decision-making position with respect to a 25 where I -- what I -- the advice that I'm

Page 46 Page 48 1 giving is actually something that I know 1 So it's -- first off, you would actually happened. Sometimes you give advice 2 2 use the common English language definition. 3 to companies, but it doesn't -- we have no 3 I don't believe that those -- I haven't seen 4 4 idea whether the company actually follows our a definition separate within the regulations. 5 5 advice. Sometimes there will be. б 6 Q. My question is slightly So based on that and my 7 different, Dr. Plunkett. 7 experience and the looking into what others 8 If you were to give advice to 8 have described about this, this is the idea 9 the company that you've referenced as having 9 of considering how the product is used, is 10 experience with cosmetic regulation 10 one of the -- one of the concerns that you 11 compliance that that company chose not to 11 have, and whether or not the -- based on how follow, that company has the ability to 12 12 the product is used and how the product is 13 ignore your advice, correct? 13 being sold, that in order to prevent a health A. Yes, I would imagine that they hazard, a warning hazard -- a warning 14 14 15 could do that. 15 statement would be needed. 16 Q. Okay. Have you ever drafted 16 Q. Can you cite to me any language 17 regulations that relate to cosmetics? 17 within the regulation or even supporting A. Actually drafted a regulation? 18 documentation, a comment, something of that 18 nature, that would define "whenever necessary 19 No, I have not. 19 Q. All right. You reference in 20 20 or appropriate" with respect to how the 21 your report language out of 21 CFR 740.1, and 21 product is used? 22 specifically -- you reference it in a few 22 MS. PARFITT: Objection. places. And I can direct you specifically to THE WITNESS: I don't think I 23 23 paragraph 22 in Exhibit 4. 24 24 understand your question. A. Yes. I'm there. 25 Are you asking me to cite to a 25 Page 47 Page 49 1 Q. All right. And do you see here 1 reference or a part of the regulation 2 you have replicated language from 21 CFR 2 where they explain it, or what are you 3 740.1 that reads, "The label of a cosmetic 3 asking me? Guidance document or -product shall bear a warning statement 4 QUESTIONS BY MS. BRANSCOME: 4 5 5 whenever necessary or appropriate to prevent Q. Yes. Can you point me to 6 anything other than your personal view of the 6 a health hazard that may be associated with 7 7 interpretation of this language that would the product"? 8 8 Do you see that? tie the requirement "whenever necessary or 9 appropriate" to how a product is used? 9 A. Yes. 10 Q. And you added emphasis on 10 MS. PARFITT: Objection. Form. 11 particular portions of this sentence, 11 THE WITNESS: I'll have to go 12 12 correct? look for you whether there's a 13 13 guidance that states it that way. Yes, I did that, exactly. A. Q. All right. Now there's a 14 This is based on my experience in 14 dealing with the products in the past. clause in this sentence that states, 15 15 16 "Whenever necessary or appropriate." 16 I think that's also consistent 17 Do you see that? 17 with what is described, I would say to 18 A. Yes. 18 you, within -- it's consistent -- what 19 19 I'm describing to you, it's consistent Q. You did not emphasize that 20 language; is that correct? 20 as well with how the CIR standard for 21 A. That's correct, I did not. 21 safety assessment is done, looking at 22 O. What is your understanding 22 the issue of the -- of the -- of the as -- what you describe as an FDA regulatory 23 23 use. 24 specialist of the meaning of "whenever 24 **OUESTIONS BY MS. BRANSCOME:** 25 necessary or appropriate" in 21 CFR 740.1? 25 Q. When you say that you're basing

Page 50 Page 52 1 your interpretation of the clause "whenever 1 look at my documents in order -- the 2 necessary or appropriate" on your personal 2 first part of your question, I'd have 3 experience, can you point me to something 3 to go back and look. Off the top of 4 my head, I can't tell what I would 4 specific? 5 MS. PARFITT: Objection. 5 point you to. 6 6 THE WITNESS: Are you asking On the second one, I think I me -- are you asking me if I've ever 7 7 was telling you, is I don't -- I've 8 had a company that I worked for that 8 never -- I don't have a client that 9 that particular clause in here was 9 I've worked for where that part of the 10 10 extremely important to how we language was the only issue that I had interpreted it? I don't think I can to deal with when I'm looking at 11 11 point you to that. I don't recall 12 12 whether or not the product needs a ever having to do that specifically. 13 13 warning or not. 14 Or is it something different 14 So typically -- I'm just you're asking me? 15 telling you that when I have looked at 15 16 QUESTIONS BY MS. BRANSCOME: 16 labeling for products and looked at 17 Q. Dr. Plunkett, I asked you what 17 the issue of does it need a warning your basis was for interpreting the language 18 18 statement, when I'm reading it as 19 "whenever necessary or appropriate" means 19 "whenever necessary or appropriate," that it's related to how a product is being I'm looking at whether or not the 20 20 21 used, and the answer that you provided was 21 ingredient that I'm concerned about that it was based off of your personal within the product, how that is used 22 22 23 experience. 23 or what the exposure pattern would be, 24 So I'm asking you, what is that 24 route of exposure, how those things personal experience that gives you the basis might relate to how I would assess the 25 25 Page 51 Page 53 1 for that specific interpretation? 1 safety issue at hand. And so that's 2 MR. MEADOWS: Objection. 2 what I'm trying to tell you. 3 MS. PARFITT: Objection. 3 QUESTIONS BY MS. BRANSCOME: THE WITNESS: So it's in my 4 Q. Okay. You also have --4 5 5 experience in dealing with companies changing topics a little bit, in this -- in that make products and what types of 6 your report marked as Exhibit 4, if you could 6 7 7 warnings are put or not put onto -- or turn to paragraph 10. 8 8 not -- or on labeling. So I don't On page 7, you state on the 9 know how else to answer it other than 9 first paragraph on page 7, "In other 10 that. 10 instances I have directed others to perform 11 I can go back and look at the 11 searches on my behalf," and this is with 12 respect to identifying documents for review 12 guidance documents to see if that is described in another way, but I don't 13 in forming your opinions. 13 14 14 What did you mean by that? recall that. 15 **OUESTIONS BY MS. BRANSCOME:** 15 A. So in addition to doing my own 16 Q. So as you sit here today, 16 searches of the database, sometimes I -- I 17 you're not able to provide me either with a 17 have called the attorney's office and asked 18 third-party document or an independent 18 them to -- to do a search for certain things 19 document interpreting "whenever necessary or 19 that I'm looking for to add to. So in other 20 appropriate" as you've suggested today, nor 20 words, I have a document I've identified. 21 can you give me specific example from your 21 I'm looking for other documents like that in 22 22 personal experience; is that correct? the large millions and millions of documents 23 MS. PARFITT: Objection. that are available. And so sometimes I will 23 24 THE WITNESS: Well, I 24 ask attorneys to do -- to look in the 25 certainly -- I'd have to go back and 25 database for other documents like the ones

Page 54 Page 56 1 that I've identified. 1 A. So that might cross over into 2 Q. And without getting into 2 work product because it's not my database, 3 anything that would be -- that would call for 3 but I don't know how to answer that. I mean, information protected by the attorney/client 4 4 I'm sure -- it's very possible that in the privilege or attorney work product, what 5 5 database you can track that, but I -- I don't percentage of the overall searches for 6 6 know. relevant documents from these particular 7 7 MR. MEADOWS: Okay. 8 databases that are discussed in paragraph 10 8 THE WITNESS: I don't have 9 would you say that you have done yourself as 9 anything saved on my computer that 10 opposed to directed others to do? 10 way, but when you go to the database A. Well, initially when I first 11 itself, it's possible you could track 11 12 started searching, those were my own searches 12 that. I just don't have a record on 13 exclusively. I would say that more recently, 13 my computer in my office. in the last year, since I haven't added any QUESTIONS BY MS. BRANSCOME: 14 14 15 real new areas but there's new documents that 15 Q. When you made the decision at 16 have become available, so anything -- any of 16 some point in time -- it may have been even 17 the searches probably in the last year that 17 prior to you issuing your first report -dealt with new discovery that was produced, I 18 that you wanted to look at company documents, 18 19 would have asked the attorneys to do some of 19 did you set out specific categories of the searching in that for me. Like I'm 20 documents that you wanted to review? 20 21 looking for documents that are similar to 21 A. Not so much categories but key 22 this document that I cited in my original 22 words. So -- and areas. I guess areas is report around this same frame that may be 23 what I -- yes, I was focusing, for example, 23 24 discussing this same topic area. 24 in my initial report on documents that 25 So in the last year I have 25 described what was known -- what the company Page 55 Page 57 1 asked them to do that more than I have done 1 was discussing about cancer, ovarian cancer, 2 it, but initially it was what I did 2 cancer generally. So that was a key word 3 initially. 3 used. 4 4 Okay. Do you keep any records And then I also was linking O. 5 of the various document searches either that 5 that in different searches with different you have performed or you have asked to be 6 6 time periods such as the NTP review process 7 performed? 7 and dates. You can, you know, narrow down by 8 8 dates or by the CIR process. Those kinds of A. No, I don't. My record would 9 be -- the initial -- the record would have 9 things. 10 been what I listed in my reliance list for 10 So I did start with that, 11 you in the initial report, but since then it 11 trying to understand what -- what is -- what 12 would just be what is going to be changing 12 was in the company files or in the files I within my reliance list, looking at 13 13 had access to, the database, that dealt with additional documents. That's the only way I 14 14 those kinds of things because those aren't 15 could identify for you. That would be my --15 things that I could get to publicly. 16 my trail to know what was new and what was 16 Obviously in the literature. So I had to --17 not. 17 if I wanted to understand what the company 18 Q. My question is slightly 18 knew, I had to go into their database to find 19 different. Understanding that you have 19 out, you know, what they knew -- what they 20 provided to some extent a record of the knew or were discussing over time about the 20 21 documents, my question is: Do you have any 21 ovarian cancer issue or about asbestos in 22 type of record for the nature of the talc or about CIR process, things like that. 22 searches, what it was that you set out to 23 23 Q. Using the reports that you have 24 identify in the database and how did you go produced, Exhibits 2, 3 and 4, really, and 24 25 about finding those documents? 25 the full -- the entirety of the materials

Page 58 Page 60 1 that you have produced in the MDL, is there 1 reliance list, that you read, but then once 2 any way that someone reviewing those 2 you started reading decided weren't relevant 3 documents, and those documents alone, could 3 to the opinions that you were offering? 4 4 A. I would have to look to answer replicate the searches that you have 5 5 conducted in the company databases? that for you. I don't know. If you want me 6 6 MR. MEADOWS: Objection. to do that, I'd have to look. 7 7 THE WITNESS: I don't know. Q. I ask you more as a process 8 That's a good question. I've never 8 matter. 9 thought about whether you could 9 A. Oh. 10 10 replicate or not. Q. If you pull an article and you I mean, I think I've told you 11 start reading it and you realize that it is 11 not relevant to the opinions that you offered 12 what I did. My strategy was to focus 12 13 on topic areas. So I think you 13 in this case, the example that you just gave, is it something that you would include in 14 might -- by topic areas, if you use 14 15 the same kinds of topics areas as 15 your reliance list? 16 described, I think you would come up 16 A. Yes, I -- I have given you 17 with documents that -- what it focused 17 everything I retrieved. So if I retrieved 18 it, you would have, yes, absolutely. 18 down to. Q. Okay. So it's fair to say of 19 For example, I also would 19 20 20 the articles that are on your reliance list, sometimes, as linking those words, I 21 might put in J&J documents only or 21 you could not say as you sit here today that 2.2 Imerys documents only, because the 22 you have read each and every word of each and database has a variety -- and the every one of them, correct? 23 23 A. That's correct. And I could 24 PCPC. There's some different ways by 24 25 25 the Bates numbers that you can probably tell you -- I could give you a Page 59 Page 61 1 segregate documents as well. But I 1 little guidance in that possibly if I went to 2 don't know other than that. That's 2 my list, I could try to pull some out that I 3 all I can tell you. 3 recognize, but that's all I would be able to 4 QUESTIONS BY MS. BRANSCOME: 4 do for you. 5 5 Q. You would agree with me that Q. Okay. How did you go about 6 identifying what articles you wanted to 6 your report does not contain a complete 7 7 review in forming your opinions in the MDL? explanation of the process by which you 8 A. So first off, I went back to 8 identify company documents to review, 9 9 correct? what I already had. So my MDL report is a --10 A. I haven't laid out my search 10 is a compilation of a lot of material that's 11 11 in my first few reports. That was the basis structure, that is true. 12 for some of the things that went into it. 12 Q. All right. Now, the articles 13 that you have listed on your reliance list, 13 So I didn't -- I did do, 14 have you read each and every one of those 14 though, a updating on literature searches for 15 articles? 15 the MDL report, looking for anything new, for 16 A. Unfortunately, yes, over time I 16 example, in the area, especially the area of 17 have. Some of them I have only read parts of 17 cancer data or reports of dealing with 18 them. For example, if I started reading a 18 ovarian cancer either -- or any articles 19 document and I felt that it was something I 19 dealing with the link between inflammation 20 pulled that really wasn't directly on point 20 and cancer, ovarian cancer, generally. 21 21 for an area I'm covering, I may not have read That's one of the areas I updated looking at. 22 every word, but certainly I have been through 22 And then I did -- I don't think 23 23 each of those, yes. I did any large, new searches, however, 24 Q. Are there any articles in your 24 because honestly the areas covered here are a 25 reliance list, that you maintained on your 25 little narrower than what was covered here.

Page 62 Page 64 1 I don't believe that there was any from the 1 referring to the reliance list, are you referring to the list of articles that begins 2 published -- the publicly available medical 2 3 literature. There wasn't a need to do a 3 on page 40 of Exhibit 4, or is there a 4 whole new area of search. It was more separate document? 4 5 5 updating the things that I've done in the A. There's a separate document. б 6 So it -- that's -- I usually call reliance 7 7 list the separate document. I call this So it's a real easy search to 8 update because you can just put in talc and 8 references cited. So I apologize for that 9 cancer and just look at -- get lots, but you 9 confusion. can then just start chronologically and look 10 10 So these, I have read every what was published in the last year, for 11 word. If it's in my reference list, those 11 12 12 are not an issue of not having read every example. 13 Q. Okay. Earlier when we were 13 word, and these should all be cited somewhere discussing the fact that you in some 14 14 in the report. 15 instances have asked your husband to pull 15 Q. Okay. If you could turn to 16 articles, have you maintained any records of 16 paragraph 21 in your initial report. the searches that you have done with respect A. Yes, I'm there. 17 17 Q. Okay. So we're looking at to scientific literature, including the 18 18 searches that you have asked your husband to paragraph 21 in Exhibit 2. This is on 19 19 20 do? 20 page 10. 21 A. I have not. It's possible that 21 Do you see there is a sentence 22 there are records on billing from the library 22 here that refers to -- it's referring 23 that tells you how many I ordered at 23 generally to the topic of the ability of talc 24 different times, but that is the only 24 to migrate from the site of application to 25 records, because we do have to pay the 25 the ovaries. Page 63 Page 65 1 library for the retrieval. Do you see that? A. Yes. 2 Q. Okay. And if I understood what 2 3 you said earlier correctly, you indicated 3 Q. And then the next sentence 4 that any article you have ever pulled for 4 states, "This issue was discussed by 5 5 review, you have listed on your reliance scientific and regulatory bodies that review 6 list: is that correct? 6 the toxicokinetics of talc." 7 7 A. Yes. And when I -- and let's Do you see that? 8 8 just make sure we're talking about the same A. Yes. 9 thing. 9 Q. And in parentheses it 10 So, you know, in my reports I 10 identified EPA 1992, IARC 2010, and CIR 2013. typically have articles cited in the report 11 11 Do you see that? separate from the reliance list. So I'm 12 12 A. Yes. 13 talking about the reliance list, right? Okay. And then if you could 13 14 turn to Exhibit 4, which is your MDL report, Okay. 14 15 at paragraph 43. It's on page 28. So -- because I do -- I do 15 16 usually -- I don't know whether I did that in 16 Are you with me? 17 this report, but I typically have a list of 17 A. Yes, I am. 18 articles cited at the back called references, 18 O. You see that the exact same 19 that is, things that you're actually seeing 19 sentence appears -- well, not the exact same. 20 in the report body, and then there should be 20 It's been slightly modified to combine the 21 a separate reliance list sent to you as an 21 first two sentences. But here you cite only 22 appendix. I don't know what the appendix 22 to EPA 1992 and IARC 2010. 23 was. 23 Why did you remove CIR 2013? 24 Q. Well, so then let's clarify 24 A. Because of my further 25 that. So, Dr. Plunkett, when you're 25 evaluation since my initial report in 2016 of

Page 66 Page 68 1 the process that was involved in the drafting 1 another question. In paragraph 43, you added 2 of the CIR and the actual production of the 2 two studies from your prior -- that were --3 report. 3 that did not appear in your prior report, and 4 4 Q. Is it your position that the it was Gardner 1981 and Edelstam 1997. This migration of talc was not evaluated as part 5 5 related to animal studies showing that in 6 6 of CIR 2013? some species talc can migrate from the lower 7 A. No. That's not my position, 7 to the upper genital tract? 8 8 A. Yes. no. 9 O. Okay. And so would the 9 Q. Okay. Were those studies that 10 sentence that's contained in paragraph 43 in 10 you were aware of before drafting your prior Exhibit 4, which is your MDL report, if you 11 11 reports? cited to CIR 2013 in the parenthetical there, 12 12 A. I don't know that they -- I 13 would that not be an accurate citation? 13 can't answer that without looking at my 14 reliance materials for the original report. I believe it would not be an 14 15 accurate citation because I have formed 15 I did identify additional articles, and 16 opinions about the reliability of that 16 there's also additional articles cited here 17 document at this point in time. 17 in earlier paragraph 43 that were not cited So it has to do with -- I'm 18 in my original report as well. I don't think 18 citing to authorities here that I believe are I had the -- the Kunz article then cited. 19 19 20 reliable as far as the discussion that I see. 20 I'd have to go back and look. 21 and it's a different -- I have a different 21 So it's possible that they were 22 opinion now about the CIR report, which I lay 22 in my -- when I say my reliance materials, my 23 23 original report also had a larger list of out in pretty detail, I think. 24 In fact, if you go to my 24 literature I didn't cite. So I'd have to 25 section following this now in -- you'll 25 look. I can't tell you whether I had them or Page 67 Page 69 1 understand one of the issues I had was the --1 I did not. 2 the difference in the evidence that was 2 Q. Okay. With respect to Edelstam 3 actually available once you dig into it a 3 1997 study, do you happen to know the title 4 little further versus what they actually 4 of that article? Even an approximation would 5 5 reviewed. That's one of the issues. work. 6 6 Q. And I'll follow up with some A. It'll be -- should be back 7 7 more questions about the CIR, but my question here. Just a second. If it's not here. 8 here is, the sentence in your report simply 8 that's a mistake. 9 9 states, "The migration of talc internally Oh, here it is. "Retrograde 10 after perineal application was discussed by 10 migration of starch in the genital tract of scientific and regulatory bodies that review 11 rabbits." 11 12 Q. So you are citing that article 12 the toxicokinetics of talc." for the proposition that animal studies have 13 13 Would it be inaccurate to say 14 demonstrated that talc can migrate from the 14 that as part of the CIR 2013 process that lower to upper genital tract? 15 15 body did, in fact, discuss the migration of 16 talc internally after perineal application? 16 Yes, I'm citing it because it's A. It is true that they did 17 relevant to the issue of particle migration, 17 18 which talc is a particle. So, yes, that's 18 discuss it. I just have an issue with the 19 19 reliability of their findings. 20 Q. Okay. But that study did not 20 And so you made the decision to specifically deal with talc migration, 21 just remove it from the citation; is that 21 22 correct? 22 correct? 23 23 A. Yes, at this point -- at this A. No. Well, it -- it's relevant 24 point, at this report, that's exactly right. 24 to talc migration, but you're exactly right, Q. All right. And then I had 25 they looked at the starch migration, yes. Or 25

	Page 70		Page 72
1	particles that were starch, yes.	1	genital tract?
2	Q. We'll cover this in more	2	MS. PARFITT: Objection.
3	detail, but is it your opinion that all	3	THE WITNESS: Again, I haven't
4	particles have similar characteristics with	4	done an in-depth analysis. I mean, as
5	respect to their ability to migrate in the	5	a toxicologist, there are differences
6	genital tract?	6	between starch and talc, absolutely.
7	A. It's my I don't know if I'd	7	For example, starch would I would
8	state it quite that way. What I would say is	8	expect to be more easily solubilized
9	that the evidence shows that particles	9	within fluids, and so that could
10	generally have the ability to move up the	10	affect the ability of them to actually
11	reproductive tract in women, yes, and that if	11	not migrate as well as a talc
12	a particle is one that is similar to talc or	12	particle, which would be less soluble
13	some of the other ones where the information	13	than the starch would be.
14	has been collected, I would characterize that	14	And there's I even
15	as being within that, quote/unquote,	15	there's a paper I have in here, and I
16	relevance of particles.	16	can look for it if you want, that
17	That doesn't mean all	17	talks about that difference, and it's
18	particles, but certainly in the ones that I	18	one of the issues of cornstarch versus
19	have looked at and the data I've relied upon,	19	talc, on whether or not you would
20	there's a variety of different types of	20	expect to get the long-term chronic
21	particles or substances that have been	21	responses with the difference between
22	studied and shown to be able to migrate.	22	those two substances.
23	Q. So let's take Edelstam 1997 as	23	So I do think there's
24	an example.	24	difference, absolutely, as
25	Did you do any analysis that	25	toxicologists generally. And the only
	Page 71		Page 73
1	you can point me to that establishes that	1	reason I'm citing this paper is
2	starch would have a similar migration pattern	2	because I'm trying to be complete
3	as talc?	3	about people that have looked at this
4	A. So I would say that the paper	4	issue. And certainly it was a study
5	itself shows talks about the movement of	5	that looked at this issue and talks
6	starch, but are you asking something	6	about the movement.
7	different?	7	But I wouldn't expect starch
8	Are you asking me have I done a	8	and the talc to have the same
9	specific analysis of any differences that may	9	liabilities, and I also wouldn't
10	occur between the migration pattern of starch	10	expect them to move exactly the same
11	and talc? Is that what you're asking me?	11	speed maybe. That's very true.
12	Q. That is what I'm asking you.	12	QUESTIONS BY MS. BRANSCOME:
13	A. I certainly didn't do an	13	Q. So you would agree with me that
14	in-depth analysis of the differences, no, but	14	Edelstam is not a study demonstrating that
1		15	talc can migrate from the lower to upper
15	based upon my review of the literature, I	1 13	tale call illigiate from the lower to upper
15 16	believe that that paper is relevant to the	16	genital tract, correct?
		I	
16	believe that that paper is relevant to the	16	genital tract, correct?
16 17	believe that that paper is relevant to the overall question of migration of particulate	16 17	genital tract, correct? MS. PARFITT: Objection. Form.
16 17 18	believe that that paper is relevant to the overall question of migration of particulate through the reproductive tract, including particles of talc.	16 17 18	genital tract, correct? MS. PARFITT: Objection. Form. THE WITNESS: I wouldn't say it
16 17 18 19	believe that that paper is relevant to the overall question of migration of particulate through the reproductive tract, including particles of talc.	16 17 18 19	genital tract, correct? MS. PARFITT: Objection. Form. THE WITNESS: I wouldn't say it that way. What I would say instead is
16 17 18 19 20	believe that that paper is relevant to the overall question of migration of particulate through the reproductive tract, including particles of talc. Q. Regardless of whether or not it	16 17 18 19 20	genital tract, correct? MS. PARFITT: Objection. Form. THE WITNESS: I wouldn't say it that way. What I would say instead is that Edelstam is a study that forms
16 17 18 19 20 21	believe that that paper is relevant to the overall question of migration of particulate through the reproductive tract, including particles of talc. Q. Regardless of whether or not it was an in-depth analysis, can you point me to	16 17 18 19 20 21	genital tract, correct? MS. PARFITT: Objection. Form. THE WITNESS: I wouldn't say it that way. What I would say instead is that Edelstam is a study that forms the overall weight of the evidence for
16 17 18 19 20 21 22	believe that that paper is relevant to the overall question of migration of particulate through the reproductive tract, including particles of talc. Q. Regardless of whether or not it was an in-depth analysis, can you point me to anything other than just your belief after	16 17 18 19 20 21 22	genital tract, correct? MS. PARFITT: Objection. Form. THE WITNESS: I wouldn't say it that way. What I would say instead is that Edelstam is a study that forms the overall weight of the evidence for the ethics for the studies that are
16 17 18 19 20 21 22 23	believe that that paper is relevant to the overall question of migration of particulate through the reproductive tract, including particles of talc. Q. Regardless of whether or not it was an in-depth analysis, can you point me to anything other than just your belief after having read these articles that starch and	16 17 18 19 20 21 22 23	genital tract, correct? MS. PARFITT: Objection. Form. THE WITNESS: I wouldn't say it that way. What I would say instead is that Edelstam is a study that forms the overall weight of the evidence for the ethics for the studies that are available that address the issue of

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1	with you there.	1	assessment.
2	Unfortunately, the majority of	1 2 3 4 5 6 7 8 9	Q. Okay. What publication would
3	the information that I have relied	\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\	you direct me to that has used the same
4	upon, and others such as the FDA in		methodology that you have used to reach your
5	making their statements about		opinions in Exhibit 4?
6	migration, is not all directed studies		A. I think I cite you to cite
7	just to talc. It's looking at the		you to some of those. You could well, the
8	issue of particle movement.	8	directly relevant one would be looking at the
9	QUESTIONS BY MS. BRANSCOME:		chapter on risk toxicology in the
10	Q. Now, in terms of doing your	10	reference manual on scientific evidence.
11	risk assessment well, let me get back. We	11	You can also go to the NRC
12	covered this earlier, and I want to return to	12	report where they it lays out the
13	it for a moment. Just to confirm: For your	13	different steps that you use when you kind of
14	work in the MDL, you did not do a Bradford	14	break data apart into exposure versus
15	Hill analysis, correct?	15	response information.
16	A. I did not sit down and do a	16	And then I cite to there are
17	Bradford Hill analysis when I started writing	17	some guidance documents that I cite to, and
18	this report. I have done a Bradford Hill	18	this is in paragraph 13. And I'd have to
19	analysis in the past, which is in my original	19	pull them out again to tell you which ones
20	reports, but I certainly did not redo a	20	relate to different pieces because some of
21	Bradford Hill when I sat down to draft my MDL	21	these are some of these documents are
22	-	22	
	report, that is true.		specific to only, for example, maybe one part
23	Q. Okay. Let me be more precise.	23	of what I did.
24	In the report that you have	24	But certainly the risk
25	produced that contains a description of your	25	assessment process at IARC is they do what
	Page 75		Page 77
l 1	oninions in the MDL, you have not set forth a	1	Lcall a hazard assessment. They identify
1 2	opinions in the MDL, you have not set forth a	1 2	I call a hazard assessment. They identify
2	Bradford Hill analysis in that document which	1 2	hazard and they couldn't quantify risk, but
2 3	Bradford Hill analysis in that document which is identified as Exhibit 4, correct?	1 2 3	hazard and they couldn't quantify risk, but the steps they go through are essentially the
2 3 4	Bradford Hill analysis in that document which is identified as Exhibit 4, correct? A. That is true, yes.	1 2 3 4	hazard and they couldn't quantify risk, but the steps they go through are essentially the same types of steps that I went through as
2 3 4 5	Bradford Hill analysis in that document which is identified as Exhibit 4, correct? A. That is true, yes. MS. PARFITT: Objection.	1 2 3 4 5	hazard and they couldn't quantify risk, but the steps they go through are essentially the same types of steps that I went through as far as gathering data on not just response
2 3 4 5 6	Bradford Hill analysis in that document which is identified as Exhibit 4, correct? A. That is true, yes. MS. PARFITT: Objection. QUESTIONS BY MS. BRANSCOME:	1 2 3 4 5 6	hazard and they couldn't quantify risk, but the steps they go through are essentially the same types of steps that I went through as far as gathering data on not just response but also the potential for exposure and how
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process as I review each piece of information, and that is what you do as part of weight of the evidence. You gather all of the relevant information that you can find that address the question you're trying to answer, and since I'm looking at both exposure and response, I gather different pools of information. Q. You would agree that there are ways to do a weight of the evidence assessment of published literature that assign, for example, quantitative values to particular pieces of evidence, correct? A. Certain individuals have put together, but there's no one general accepted process that everyone uses. So I that's the issue. Again, there are certain certain cases where I've seen that done, and then there are many most cases that it's not what's done. Q. Okay. A. Another body, by the way, that I it's new. It's not in paragraph 13. I just want to make sure I tell you that so we're clear. If you look at the Canadian	Q. Okay. As you were forming your opinions, Dr. Plunkett, about whether or not there is a risk associated with the use of Johnson's baby powder with respect to ovarian cancer, how do you keep track of the pieces of scientific evidence that you have reviewed and the respective weight that you give to them? Presumably you did not read everything in one day, for example? A. No. That's correct. So I typically will I typically will save the papers when I read the papers, I will often highlight in yellow information that I think is going to will be extremely relevant. I don't put notes on the document. I highlight in yellow on the PDF file to use that to write. And I also start drafting report very early, which then gets overwritten and actually ends up looking like an outline that eventually becomes the report. So one of the ways I keep track of things is I may put a paragraph name that
document, they also in fact, a lot of what they have, you'll see the same literature described within my assessment as well. Q. So using the Canadian assessment as an example, for instance, in that assessment there were actually values assigned to particular pieces of literature, correct? A. Mainly the epidemiological literature, that is true. Again, but I'm not doing causation, so I didn't approach it that way. But certainly if you look at what I did, it's consistent with that because I talk about the differences between the limitations of a case-control versus a prospective study. I talk about both the positives and the negatives within the database, but I don't lay it out in a table like they do. But it's certainly the same basic process. I was actually quite surprised at how similar the database of information that they reviewed was to what I honed in on as well.	I know I'm going to write, such as exposure migration, and then I as I'm reading a paper, I'll type in a paper the ones that I believe are important to my overall assessment. So I will do that as I'm as I'm going through the evidence. So that's one of the tools I use, but I don't keep notes. I just kind of use that as a living document that eventually becomes a report. Q. Do your opinions ever change as you read additional pieces of scientific evidence? A. Yes, it does. It may change. And it often often the changes, though, are not that I believe with the exception of epidemiology. In other areas. Epidemiology is a little bit different issue when you're reviewing studies. But on toxicology I always start with reviews and regulatory authorities, looking at what others have said generally about the toxicology. And so even though I may refine opinions differently or I might change, I certainly wouldn't agree to

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work on a project to start with if my initial reviews on hazard, for example, didn't convince me that I believe that there is a hazard. But you refine it from there. That's exactly right. So there are cases, however, where I'm asked to work on a project where there is no review or regulatory authority or any kind of assessment over a period of years, and in those cases there are times when I start working on a project and I stop and say, "I can't do this." Because that happens, yes.	your report that have been criticized by others at some point in time, correct? A. Yes, that's true. Q. Okay. Now, in some instances you state that you then give little weight to those studies, correct? A. Yes. Q. But in other instances you find the criticized study to be helpful and informative, correct? A. That's true. Because, again, judgment as anybody does weight of the evidence, different scientists can have
So opinions do change sometimes based on review of additional information. Q. Is there any documentation that you've produced either in your report or otherwise in the MDL that would allow some reviewing the material to understand the order in which you reviewed materials or the specific weight that you assign them? A. So order of review, no. I don't think you would know that other than you will note order of review if you look at the differences in the literature cited in my	different judgment. Mainly, I think, when I look at the differences in that in that regard, I think you should pay attention to what the
original report versus in the MDL. So in my original reliance list, if there were documents that weren't there and they're now here, obviously that tells you it was a review. On the issue of a of the weight of the evidence process, the only answer I can give you for that is that articles that I believe are are reliable, are relevant and are those are kind of the you look at the reliability of the studies, whether they're peer-reviewed or not or if they have proper controls put into place, things like that, whether or not the they're relevant to the question at hand. That you can get from looking at how discuss them in the document. But certainly there's no, like, summary of that. But certainly I think you understand you should understand when you read my report what weight I'm giving based on how I'm describing those those	about risk versus how an epidemiologist might talk about risk. Q. Could two different toxicologists review the same piece of literature and give it very different weight? A. I don't know about different weight, but they certainly I know people come to different conclusions based on their overall assessments. That happens, definitely. I mean, there are always going to be individuals that look at things differently. I know in this case there are people I've seen defense experts that reports in not in the MDL but in other cases, where people disagree with some of my opinions, and I disagree with their opinions. That happens. Q. Okay. And so if I were well, let me just ask something. You have

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Misstates her testimony. MR. MEADOWS: Objection. THE WITNESS: So I don't report for you a table where I quantify that, that is correct, but certainly that is because, again, based upon looking at the way that I was trained and the documents that I'm talking I'm pointing you to to describe how to do weight of the evidence, it is not it is not a numerical exercise, how many here, how many there, this one gets 5 points because of this or 6 points because of this. It's more an issue, again, of judgment. It's the idea of looking across all of the available information and determining whether or not, based on that, it's your opinion that there that, for example, talc talc's toxicity profile includes cancer. That's one of the judgments weight of the evidence judgments you make, for example.	The robustness of the data. The robustness of the data. For example, the NTP GLP quality animal study, very high quality in the weight of the evidence. And I talked to you about that. In fact, it even though people criticize that study, that study is very valuable for looking at biologic changes that are consistent with a carcinogenic mechanism being initiated. So even though you may say that you can't quantify risk from that animal study as far as calculating a cancer potency factor, what you can do is use that study of high quality to make judgments within a weight of the evidence for risk. QUESTIONS BY MS. BRANSCOME: Q. Dr. Plunkett, you understand I have seven hours today, and I while I'm very interested in the answers that you give, if we could just we will get to things like NTP when we get there, if you could just attempt to answer the question that I've
QUESTIONS BY MS. BRANSCOME: Q. So but, Dr. Plunkett, just to be clear, you do not provide a numerical value to the particular pieces of evidence that you have considered as part of your weight of the evidence assessment in the MDL, correct? MS. PARFITT: Objection. Form. THE WITNESS: So I do not provide a numerical value as you see it laid out, for example, in the Canadian table, but certainly I do judge articles that I include in my weight of the evidence based on a system that includes different considerations such as like I said, peer-reviewed or not, that makes an issue. Whether or not the study that's being reported is the only one the first or is this something that is that is describing an assessment that's been done by someone else and so you see a repetition or a consistency among the studies that	asked. I simply asked the question: Are there numerical values assigned to the particular pieces of evidence that you have considered as part of your weight of the evidence assessment in reaching your opinions in the MDL; yes or no? A. And I said to you, not in the way that it's done I assume you're referring to something like what was done what's in the Canadian epidemiology table. I have not done that, no. Q. Okay. A. That's exactly right. Q. Have you provided a qualitative chart, for example, of the evidence that you have considered in forming your opinions in the MDL? MS. PARFITT: Objection. Form. THE WITNESS: I don't know what you mean by qualitative chart. I certainly have I certainly, I believe, have given you qualitative descriptions of my weight within my discussions of each study, yes, I have

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done that. QUESTIONS BY MS. BRANSCOME: Q. You mention in response to the prior question that you have a system for weighting the pieces of evidence that you have reviewed. Can you point me to paragraphs in your report marked Exhibit 4 that would outline in detail the system that you used to apply different weight analysis to different pieces of evidence? MS. PARFITT: Objection. Form. THE WITNESS: And I think I answered that, that there's no system written down by anyone. But what there is, instead, is if you read these descriptions of use of weight of the evidence that I've cited in paragraph 13 as well as the discussion of methodology in the Canadian document, that is consistent with what I do. It's the idea that you start with a literature search for peer-reviewed, publicly available	published afterwards, and what I thought I said to you was that if you look at that document it's not in paragraph 13, but if you look at that document, it lays out a process. And I wouldn't call it a system. It's a process. It's a process by which you screen information for relevance to the question being asked and how, then, based on that, you look at characteristics of that information such as and I tried to give you some of those. And I've said this before in depositions in these cases. You know, you look at the issue of whether or not the study was peer-reviewed, whether or not there was statistically statistical significance or at least statistics applied to the data. What was the quality of the study as far as the size in order to be able to answer the question being asked. Those are the kinds of things that you look at.
peer-reviewed, puonery available	kinds of timigs that you look at.
information. You look at the quality of the studies, the statistically significant findings. Those are all things that are discussed within these documents I'm pointing you to. QUESTIONS BY MS. BRANSCOME: Q. Now, you A. But it's it's I don't know of anyone who has written down a specific system that applies in all circumstances, no. Q. Okay. Have you written down a system that applies specifically in this case? A. I think I have tried to do that for you when I describe what I did. Q. Okay. You just referenced the fact that your system can be found in the Canadian document. You agree that the Canadian analysis was actually published or produced after you had completed your report in the MDL, correct? MS. PARFITT: Objection. Form. THE WITNESS: Certainly it was	And then also the question when you're looking at a specific question, you may pull in like you asked me about the starch particle. You may pull in things that you give less weight because obviously that's not just talc, that's starch, and you have to consider that. So that is part of the process. QUESTIONS BY MS. BRANSCOME: Q. Dr. Plunkett, the question I asked you simply was: The paper that you reference that contains some detail about the Canadian analysis, that was published after you completed your report that's marked here as Exhibit 4; is that correct? MR. MEADOWS: Objection. THE WITNESS: Yes, and I believe I answered that at the start. I usually try to answer your question, and then I try to explain further some details I think are important context on my answer. QUESTIONS BY MS. BRANSCOME: Q. I understand that,

Page 94 Page 96 1 Dr. Plunkett. You have given many 1 panel; is that correct? 2 depositions. You understand I can ask you 2 A. Yes. 3 for more detail if that would be helpful to 3 And so is it your view that a Q. 4 study or an analysis that reaches a 4 5 particular conclusion should be assigned 5 If you could, just focus on the question that I asked, and we can explore 6 6 little weight if it fails to consider all additional areas if that's something I'm 7 relevant scientific evidence to the issue 7 8 interested in doing. 8 that it's evaluating? 9 Okay? 9 MS. PARFITT: Objection. MR. MEADOWS: Objection. 10 10 THE WITNESS: I think it 11 She's --11 depends on the situation, but that MS. BOCKUS: Break? 12 could be the case, yes. It depends 12 13 MR. MEADOWS: After I finish my 13 on -- on the -- depends on -- I think it would depend on each case, the 14 objection. 14 15 She's going to answer the 15 question being asked, and what was 16 question as thoroughly as she feels 16 omitted. But, yes, I think it could. like she needs to answer the question QUESTIONS BY MS. BRANSCOME: 17 17 based on the way you ask it. 18 18 Q. Okay. And in this situation 19 Want to take a break now? 19 you identify -- I believe you claimed that 20 MS. BRANSCOME: We can go off 20 eight human studies were not considered by 21 the record. 21 the CIR 2013 panel; is that correct? 2.2 VIDEOGRAPHER: We're going off 22 A. Let me look at the number, but 23 23 the record at 10:41 a.m. that sounds about right. Yes. 24 (Off the record at 10:41 a.m.) 24 Q. All right. And returning, 25 VIDEOGRAPHER: We are back on 25 actually, to your prior answer, you said that Page 95 Page 97 1 the record at 10:56 a.m. the failure to consider all relevant 2 QUESTIONS BY MS. BRANSCOME: 2 scientific evidence on a topic would lead you 3 Q. All right. Dr. Plunkett, we 3 to assign little weight to a particular 4 started talking a little bit about the CIR 4 conclusion. You said that that could happen. 5 5 analysis that was done in 2013. Under what circumstances would Am I correct you no longer 6 6 you assign a conclusion little weight for 7 7 consider that reliable? Is that your failing to consider what you consider to be opinion? 8 8 all relevant pieces of scientific literature? 9 A. Yes. 9 A. Well, I think it depends --10 Q. Okay. And you identify in your 10 well, the reason I specifically addressed 11 report marked as Exhibit 4, I believe it's 11 that in this case is because that was -- the 12 paragraph 56? 12 conclusions about migration is the main 13 Yes, that's correct. And I 13 reason why the CIR panel then draws think I talked about it later on as well, but 14 14 additional conclusions later on. 15 definitely I do here. 15 So my issue is, migration was 16 Okay. And in paragraph 56, you 16 key to what -- the decisions they made about 17 state that the CIR panel failed to account the safety issues of talc. And so in that 17 18 for all the studies that informed on the particular case, this -- this failure to 18 19 issue of migration of particles such as talc 19 consider all the evidence was extremely 20 upwards through the reproductive tract. 20 important, in my view, and I gave it little Is that your opinion? 21 21 weight. 22 22 There might be a situation 23 Q. Okay. And then you state that 23 where some -- for example, you may only look 24 because of that you assign, quote, little 24 at six or eight studies, even though there 25 weight to the conclusions reached by the CIR 25 may be dozens out there. You may have a

2.2

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reason for why you only looked at six or eight, or it may be -- and as a result you may lay that out and, therefore, you may still give weight to conclusions drawn. Or it may be that the six or eight are -- studies that you discuss are not -- the weight is not affected by what you've

2.2

omitted.

I believe that the weight is affected by what is omitted when you look at some of the articles being review articles, which give you an understanding of what was generally accepted within the scientific community when you get to reviews, those kinds of things. So it really is a case-by-case basis.

But certainly I do believe that it is possible that in another circumstance where things are omitted you would come to the same conclusion, that you give those conclusions less weight.

Q. Is there a way, if someone were try to replicate the weighting of particular evidence based upon your process, for them to know whether or not the omission of a

QUESTIONS BY MS. BRANSCOME:

- Q. Okay. Of the eight studies that you identify on page 37 of your report that you contend the CIR panel did not account for, do any of those eight studies specifically discuss the migration of talc in human subjects?
- A. No, I don't believe they do, but there are a couple of these studies that I found to be extremely important if you want me to explain that to you.
- Q. Do you break out in your report in any other paragraphs which of these eight articles you consider to be extremely important?

And if you could just point me to paragraph numbers, that's good enough if you have, in fact, broken them out.

- A. I have. I -- this whole section I break -- I talk about each one individually. So I think you can tell by what I read -- what I'm discussing what I thought was important and informative about each of those.
 - Q. Do you rank the eight studies

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citation of certain studies means that a study should be given little weight or whether it wouldn't affect the weighting of

MS. PARFITT: Objection. Form. THE WITNESS: So I think this is the issue of judgment, training and experiencing that is applied to all such assessments, and this is why different scientists may come to different conclusions. But certainly it is -- it was important to my assessment on this issue because of the prominent role that the CIR report gives to their conclusions here for why they then drew conclusions about safety. And so that link was extremely important.

that scientific article?

MS. BRANSCOME: Can we pause for just a moment?

VIDEOGRAPHER: We are going off the record at 11:00 a.m. (Off the record at 11:00 a.m.)

VIDEOGRAPHER: We are back on the record at 11:01 a.m.

in any way by their importance to you?

A. Not with any numerical rank, no, but certainly I think I do that for you when I talk about the studies. I give you an understanding of ones that I think are particularly informative and ones that are not.

So, for example, I weight the human data -- I think I tell you that -- more than the animal data because of the differences between the reproductive tracts of humans versus animals generally, upright versus -- upright and habits and things that humans do that relate to insertions in and out of the reproductive tract, I guess is a nice way to describe it, versus an animal, that those can have, and then also the differences between animals and humans in terms of bursal sac around the ovary, those kinds of things.

So I do -- that -- I guess that ranking I do give you here. I tell you that I think these -- I think that the most relevant are going to be the human studies versus the animal studies.

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26 (Pages 98 to 101)

Page 102 Page 104 1 Right. 1 So what I do is, when I'm 2 So my question specifically is, 2 discussing about these -- all of these papers 3 where would you point me to in your report to 3 here contribute to my weight of the evidence. understand the weight that you gave each of 4 And if it's a human study, I'm giving those 4 5 5 these particular eight studies? more weight than I'm giving animal studies. A. At my descriptions of those 6 6 And that's described. 7 7 studies and what I describe. That's all I And then within papers I'm 8 8 can tell you. pulling out information that contributes to 9 Q. And I'm just asking, 9 what I think is important about what the 10 Dr. Plunkett, can you point me in the report 10 study says, and that -- and the importance of to where that discussion takes place? 11 11 what is described within the study 12 A. It takes place -- I have a 12 contributes to my weight. 13 discussion for each study, and I would -- and 13 And I don't know how else to 14 if you read what I say about each study, I 14 describe it to you. That is the process that try to go through what the strengths and 15 15 scientists go through when they evaluate 16 weaknesses of those studies are. 16 data. 17 And so those -- that would be, 17 Q. And so my question to you: 18 let's see -- you want me to give you the 18 Earlier you said of these eight studies, some starting paragraph? of them were particularly important to you. 19 19 How would I, using only what's 20 Q. So, for example, Parmley and 20 Woodruff. Can you point me to where in your 21 21 written in your report, understand which of 22 report you discuss Parmley and Woodruff, such 22 those eight studies was of particular 23 that I can understand the weight that you 23 importance to you? gave that particular study? 24 24 A. So it would have to do with 25 A. So the year of it is... what I discuss about the study. So I'm 25 Page 103 Page 105 telling you, when I -- if you look through 1 So I think I discuss it in 1 2 2 this entire section, this is the Parmley and paragraph 44, and so I describe for you what 3 important information is in there, which is 3 Woodruff paper. It is important because it 4 the information that I take as forming part 4 addresses the specific issue of movement of of my weight of the evidence. 5 environmental substances from the outside to 5 6 6 So one of the most important the inside. So I'm giving that importance in 7 7 things is what -- they have a figure they my evaluation because of what that author is show, and they're showing -- which is one of 8 8 actually discussing. the unique figures in all of the published 9 9 I don't know how else to 10 literature. But it talks about the 10 describe that. I apologize. I mean, to me, 11 differences between the female reproductive 11 weight of the evidence is a process that 12 tract and the male reproductive tract, and it 12 scientists use bringing their training and experience and judgment, and it's not a 13 shows the actual -- it talks about a 13 14 discussion of movement from substance in the 14 numerical process across the board, it just environment through -- into the vagina, into 15 is not, based on the way weight of the 15 the fallopian tubes. So it's a paper that 16 16 evidence is used within science. addresses that very specific issue. 17 17 Now, Dr. Plunkett, though, you 18 So my question to you, though, 18 would acknowledge that if you wanted to 19 is, where do you have a discussion of the 19 assign numerical values to the studies, that 20 weight that you give to these particular 20 has been something that has been done by 21 21 other authors and other authors on whom you articles? 22 22 rely, correct? So the discussion of the weight 23 has to do with the information described. I 23 MS. PARFITT: Objection. Form. THE WITNESS: I don't believe 24 don't give them a numerical ranking. I told 24 25 you that. 25 that's true. I'll need to look -- I

27 (Pages 102 to 105)

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	D 10C		D 100
	Page 106		Page 108
1	don't believe that's true with respect	1	Q. All right. And you are aware
2	to the biological information. I	2	that there is, in fact called PDQs,
3	believe it may be true with respect to	3	correct?
4	the epidemiology studies.	4	A. That's the abbreviation, yes.
5	You want me to look real quick	5	Q. Right. And you're aware that
6	to confirm that? I can do that really	6	the National Cancer Institute has in fact
7	quick, but	7	published a PDQ that addresses a potential
8	QUESTIONS BY MS. BRANSCOME:	8	connection between talc and ovarian cancer,
9	Q. I'm simply saying, could you	9	correct?
10	assign a numerical value if you chose to do	10	A. I'm aware of several that have
11	so?	11	been done over the years, but, yes, I'm aware
12	MR. MEADOWS: Objection.	12	of that.
13	Objection. Form.	13	Q. And have you reviewed those?
14	THE WITNESS: And I'm what	14	A. Yes, I have.
15	I'm trying to say to you is I think	15	Q. Are they listed on your
16	that I that there is no one set of	16	reliance list?
17	rules that you would assign in order	17	A. No, but they're listed within
18	to do that for all the types of	18	the materials as discussed within my
19	studies that you weigh.	19	depositions, and I thought and my
20	I would agree that I have seen	20	testimony. I thought that was part of my
21	it routinely done well, not	21	reliance list. I believe that it it was
22	routinely, but I've seen it done	22	in my reliance list, is encompassing all of
23	within the epidemiological community	23	the testimony as well as the actual
24	when they go through the epi data.	24 25	documents. Maybe I'm mistaken, but that was
<mark>25</mark>	But not it's not something that	25	my understanding.
	Page 107		Page 109
1	Page 107	1	Page 109
1	I've seen done when you talk about	1	Q. Okay. If they are not on your
1 2	I've seen done when you talk about weight of the evidence as part of a	2	Q. Okay. If they are not on your reliance list, should they be?
1 2 3	I've seen done when you talk about weight of the evidence as part of a human health risk assessment. That is	2 3	Q. Okay. If they are not on your reliance list, should they be? A. I believe that they are on my
1 2 3 4	I've seen done when you talk about weight of the evidence as part of a human health risk assessment. That is not something that scientists	2 3 4	Q. Okay. If they are not on your reliance list, should they be? A. I believe that they are on my reliance list by it having been pointed to as
1 2 3 4 5	I've seen done when you talk about weight of the evidence as part of a human health risk assessment. That is not something that scientists typically do as far as giving	2 3 4 5	Q. Okay. If they are not on your reliance list, should they be? A. I believe that they are on my reliance list by it having been pointed to as part of the testimony that I have given and
1 2 3 4 5 6	I've seen done when you talk about weight of the evidence as part of a human health risk assessment. That is not something that scientists typically do as far as giving numerical rankings.	2 3 4 5 6	Q. Okay. If they are not on your reliance list, should they be? A. I believe that they are on my reliance list by it having been pointed to as part of the testimony that I have given and the documents that I have relied upon during
1 2 3 4 5 6 7 8	I've seen done when you talk about weight of the evidence as part of a human health risk assessment. That is not something that scientists typically do as far as giving numerical rankings. QUESTIONS BY MS. BRANSCOME:	2 3 4 5 6 7	Q. Okay. If they are not on your reliance list, should they be? A. I believe that they are on my reliance list by it having been pointed to as part of the testimony that I have given and the documents that I have relied upon during testimony.
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Page 110 Page 112 Q. I'm not asking about your 1 1 any -- whatever portion of this is helpful to 2 opinions about what their position is. I'm 2 3 simply asking you, Dr. Plunkett, the most 3 And then if you could answer my recent NCI PDQ that you have reviewed, what 4 question, Dr. Plunkett, of what is the 4 is the position that the National Cancer 5 position as stated in Deposition Exhibit 5 6 6 Institute has taken with respect to the Number 7 of the National Cancer Institute relationship between talc and ovarian cancer? 7 with respect to the relationship between talc 7 8 A. So I would want to pull it out 8 and ovarian cancer? 9 to give you the specific statement of their 9 A. So I would be looking at the 10 position, but their position has changed such 10 section on page 12 of 18, and maybe you're that later in time they've weakened the looking somewhere else, but that's where they 11 11 actually talk about perineal talc exposure. 12 link -- their statements about the link 12 13 between ovarian cancer and genital talc use. 13 And it's under the section where they have now moved into factors with an adequate 14 So it used to be seen as a 14 15 cause, and now I believe it's not seen as a 15 evidence of an association and they describe 16 cause. I don't know the exact language, 16 it here. So they're calling it an association where the weight of the evidence 17 though. I'd have to look at it as -- maybe 17 risk factor is the better word to use. 18 is not adequate to support that association. 18 Q. All right. And so the first 19 And I need to look at the most 19 20 recent one. And that would be the best way. 20 sentence of the section under perineal talc 21 Let's just see what it says. 21 exposure states, "The weight of the evidence 2.2 Q. Okay. 'Cause is it your 2.2 does not support an association between position as you sit here today that the 23 perineal talc exposure and an increased risk 23 24 National Cancer Institute has ever issued a 24 of ovarian cancer." 25 25 statement that talc causes ovarian cancer? Did I read that correctly? Page 111 Page 113 1 A. I believe it was listed as a 1 You did read that correctly. 2 risk factor for ovarian cancer in the older 2 Q. All right. And it indicates 3 PDOs. 3 that "results from case-control and cohort 4 4 studies are inconsistent." (Plunkett Exhibit 7 marked for 5 identification.) 5 Did I read that correctly, QUESTIONS BY MS. BRANSCOME: 6 6 Dr. Plunkett? 7 7 O. I do have a copy here. Just A. You did. 8 for the sake of the record, we will mark this 8 Q. And the question that I would 9 9 as Plunkett Deposition Exhibit Number 7. ask simply is, do you discuss the National 10 Handing a copy to you, 10 Cancer Institute PDQ in the report that 11 Dr. Plunkett, do you recognize the document 11 you've issued in the MDL, which is identified 12 that I just handed you that's marked as 12 as Exhibit 4? 13 13 Exhibit 7? A. I don't specifically discuss MR. LOCKE: What's the date of 14 this document, no. I do not. 14 15 that? 15 Q. Okay. And you understand that 16 MS. BRANSCOME: This was 16 the NCI PDQ did a weight of the evidence 17 printed on December 14, 2018. 17 analysis that followed a formal evidence 18 THE WITNESS: It's -- the 18 ranking system, correct? 19 updated date is June 22, 2018, if that 19 MS. PARFITT: Objection. 20 THE WITNESS: So I -- it's not 20 helps. 21 21 laid out here, but they do have a MR. LOCKE: Yes, thank you. 22 THE WITNESS: I have seen this 22 process they use. 23 Is that what you're asking me? 23 one, yes. 24 QUESTIONS BY MS. BRANSCOME: QUESTIONS BY MS. BRANSCOME: 24 25 Q. All right. And you can review 25 Q. Yes.

Page 114 Page 116 1 1 Yes. And again, they're of epidemiological evidence? 2 2 ranking the epidemiological data, and so I A. If by -- you mean prevent, was 3 understand that that is there, yes. 3 someone stopping me from doing that, no. But Q. Now, you've said a few times 4 if you ask what would be standard practice 4 5 that you could qualitative -- you could give based on my experience, I would not be doing 5 6 6 a quantitative weight to an epidemiological 7 study, somehow suggesting that it is 7 Q. Has anyone -- and I'm not 8 8 different from other types of studies. referring in this case to any attorneys. But 9 9 What is it about a has anyone reviewed your -- the weighting 10 toxicological study, for example, that would 10 that you gave specific pieces of evidence as prevent someone from giving a quantitative 11 essentially a form of a peer review process? 11 weight in a weight of the evidence analysis? 12 A. If by that you mean have I 12 13 13 A. Because it is just what is submitted my opinions for publication, no, I 14 typically done and not done. There are 14 have not done that. Part of -- that's partly 15 certain practices within the community, what 15 driven by my understanding of the evidence 16 is kind of -- I would say that scientists use 16 that I reviewed, that some of it may not be 17 something that I should be discussing 17 routinely, or scientists have used. Not all 18 18 scientists give numerical rankings to necessarily in a public form outside of the 19 cases I'm working in. 19 epidemiological data either, because even 20 20 within a Bradford Hill assessment, when you But certainly I have not 21 21 use the considerations, there's no submitted it for publication, if that's what 22 requirement for ranking studies in order to 22 you mean. No, I have not done that. 23 meet the requirements of use of that 23 Q. Okay. Has the methodology that 24 you have used in the MDL, has that been --24 methodology. 25 25 have you submitted any type of analysis using O. Okay. Page 115 Page 117 A. But I have seen it done in the 1 1 that methodology for publication even outside 2 3 2 epidemiology community, and that is the most of particularly looking at Johnson's baby 3 common place I see it. I do not see other powder, for example? 4 toxicologists that are assessing animal 4 A. Yes, in -- if you look at my 5 6 5 studies and in vitro studies doing it that publications that describe risk assessments 6 that I have done. So the one that would come same way. 7 7 to -- to play that's similar as far as the When you do a human health risk 8 8 assessment, that isn't routine practice to do scope of the weight of the evidence would --9 9 numerical rankings on studies. at least with the animal and the in vitro 10 Q. Okay. 10 studies, would be the paper that I published 11 A. At least in my experience and 11 on copper, looking at the database of copper 12 in my training, and I was trained in the use 12 and identifying points of departure and 13 13 of risk assessment by one of the individuals target organs and risk -- risk issues based 14 who actually invented the process. 14 on copper use in humans, trying to set a --15 Q. Okay. Okay. But do you 15 understand what a safe exposure level could 16 16 consider the epidemiological evidence as part be to copper in water. And that was 17 of your risk assessment in the MDL? 17 published -- that actually was one of the 18 A. I do, because I'm looking at it 18 papers that's published with Dr. Krewski, who 19 in the context of what is out there and 19 is one of the authors of this risk assessment 20 20 in Canada. what's available. I don't always have human 21 21 data when I do risk assessments, but in this Q. And is it your position that 22 22 one I do. So I do consider them, yes. you follow the same methodology in what 23 Q. Okay. Did anything prevent you 23 you've reported in the MDL with respect to 24 from doing a quantitative assessment of the 24 Johnson's baby powder that you did in your 25 weight that you were giving different pieces 25 analysis of copper?

Page 118 Page 120 1 A. Yes, with the process of going 1 include something like the Gonzales 2016 through all of the publicly available 2 2 study, but yet you will disagree the 3 information, putting it together based on its 3 2013 -- the CIR 2013, you will give it little relevancy and reliability. 4 4 weight for not discussing particular studies? 5 5 We did a process where we So that's a very different 6 6 exercise. You want me to explain my thinking grouped it based on animal versus human, just 7 like I've done here. And we call it the 7 on that? I can do that for you, but I 8 bins, but it's the same idea. I have a bin believe that's apples and oranges question. 8 9 of human idea, I have a bin of animal data 9 My reasons for giving little 10 and a bin of in vitro data. And so, yes, the 10 weight to the CIR overall assessment versus 11 process was very, very similar. my weight or the assessment I make of an 11 12 Q. Okay. Returning back to some individual piece of data, that's different. 12 13 documents that you chose not to cite in your 13 And that's what you're describing for me. report, you do not discuss the Gonzales 2016 14 And I believe Gonzales is in my 14 15 study in your report for the MDL, correct? 15 overall reliance list, so I have read 16 MS. PARFITT: Objection. Form. 16 Gonzales. It is something that I have THE WITNESS: I'll have to considered; it's not something that I've 17 17 cited in my paragraphs. So it doesn't mean 18 look. It is not cited in the 18 it didn't go into my weight of the evidence, 19 reference list to my report, that is 19 because I do have it and I have reviewed it. 20 true. So that means it would not be 20 21 mentioned specifically in the body of 21 I just don't recall the details on it. 22 the report. 22 Is it your position as you sit 23 **QUESTIONS BY MS. BRANSCOME:** 23 here today that you know for sure that the CIR panel did not -- was not aware of or even 24 Q. You're familiar with the 24 25 25 considered any of the eight studies that you Gonzalez 2016 study, correct? Page 119 Page 121 1 A. If you want me to talk about 1 contend the omission of which makes it of 2 2 it, you'd have to pull it out for me, but I little weight? 3 know the name, yes. 3 MS. PARFITT: Objection. Form. 4 Okay. And it was looking at an 4 THE WITNESS: I would say I'm 5 99.9 percent sure, based on the 5 association between the perineal use of talc 6 and ovarian cancer, correct? 6 process that is -- that goes in. And 7 7 if you want me to explain, I'll tell A. That, I'd have to look at it to you why I feel that level of surety. 8 tell you. I believe it was a human study 8 9 9 that would be consistent with that, but I You know, I can always say that 10 need to pull it out to look at it. 10 maybe there was someone that came to 11 Q. All right. Do you, as you sit the panel that did a search on their 11 12 here today, do you know why you did not 12 own, but that is not what's done. The 13 discuss it in your report? 13 individuals that come to the panel are 14 A. I wasn't doing a full causation 14 given a body of information provided analysis in this report, so as a result I'm 15 to them in written form that they 15 review. So it's not like they -- they 16 not trying to characterize every piece of 16 17 human data. But I certainly am looking at 17 have access to anything that isn't 18 the consistency across the studies, and 18 cited in the actual report. 19 that's what I've done. 19 QUESTIONS BY MS. BRANSCOME: 20 And I mention it here. I do 20 Q. Okay. The eight articles that you discuss that are not mentioned in the CIR 21 think I mention here that there are studies 21 22 panel's work, they are publicly available 22 that came to different conclusions than the 23 2.3 pieces of scientific literature, correct? ones that I'm specifically describing. 24 24 Q. Okay. And so why is it that --A. Yes, which was why it's 25 why is it acceptable for you to choose not to 25 interesting to me that those were not grabbed

2.2

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and included within -- within the assessment done by the -- by the PCPC's group that handles CIR -- handled the CIR process here.

Q. Okay. We received just before your deposition, a few days in advance, a list of materials that have been added to your reliance list since you produced your report in this case.

Did you provide that list of materials to counsel to -- are you aware of the materials that were identified?

- A. Yes, I am. They're ones that I have reviewed since my report and -- yes, which would have been, I believed, important for you to know about, because obviously you wouldn't know if I hadn't provided that to you, and fair game for you to ask me about.
- Q. On that list was contained a number of news articles.
 - A. Uh-huh.

- Q. Are news articles pieces of scientific information that you typically consider in performing a risk assessment?
- A. No, they're not part of my risk assessment, but they -- but they were

section on the role of the industry in Section 7.

- Q. Okay. So the newspaper articles are not something that you are considering as part of your analysis of whether there is a risk of ovarian cancer from Johnson's baby powder, correct?
- A. No, that's a separate issue because it's not -- it's not scientific data, per se.
- Q. Okay. All right. Now, if you could turn to paragraph 31 in your report.

Okay. You discuss the biological effects of talc in this paragraph and in others, correct?

- A. Yes, I would call this my introductory paragraph to transition into a specific topic, yes.
- Q. Okay. And you talk here about the structure and size of talc affecting its properties.

What do you mean by that?

A. So whether it's fibrous enough, platy, fibrous. Whether it is particle sizes of less than 10 microns, less than 5 microns,

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relevant to -- they were relevant to my overall assessment of the issue of what the company is doing with regard to public dissemination of information.

So it's not the risk assessment part. It's more on the issue of the -- when I talk about the different influences of the company on public dissemination of information, I went through the different specific issues. So this would be a specific issue related to a news report that someone comes out with, the Reuters report, and then looking at what the company is saying in addition to that.

So it's understanding -- for example, the documents that Reuters discusses, many of those I'm sure I have seen, although I don't have access to -- I wasn't able to go on websites and download everything that they cite. But certainly they looked familiar, some of the ones I did

So it's that issue of -- the last part of my report, I think. Want me to tell you the section? It would be in the

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greater than 75 microns. There's different -- certain pieces of literature deal with different size ranges of talc. The smaller the size range, the more toxic it is, for example, to lung tissue; the more likely it is to be able to move, based upon the size, versus being engulfed by a macrophage if it's a larger particle, things like that.

Q. So focusing specifically on ovarian cancer, what role does size and structure of a talc particle play with respect to a risk of ovarian cancer in your opinion?

A. I don't think I formed a opinion that it has to be a specific size or structure, because the -- my opinions are related to the fact that we have a complex mixture of ingredients within the body powder, and my assessment's been on the overall consumer product, not on any one particular ingredient only within it.

So it's the idea of just understanding that size and structure of these particles are general principles that affect toxicology. So a larger particle or a

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Page 128 Page 126 1 fibrous particle may have a different tissue 1 known to affect tissue toxicity as far as 2 toxicity response than a smaller particle. 2 adverse events like inflammation and/or 3 So in other words -- I think I 3 irritation. 4 4 Q. Okay. So that's -- that's what discuss this later in a paragraph about 5 5 pleurodesis, the idea that you can get acute I'm trying to understand in more detail. 6 6 versus chronic inflammation, or respiratory What is your opinion with 7 7 distress or not. So it's just this idea of a respect to -- let's take size to start with. 8 Is there a particular size talc particle that 8 general principle that outlines how you would 9 9 think about particles generally as a is more or less likely to cause inflammation, 10 toxicologist. 10 in your opinion? 11 A. It depends whether you're 11 Q. Well, okay. So you said that 12 talking about acute or chronic. I would say 12 your assessment is based on the overall 13 for acute inflammation the larger particles, 13 consumer product. That would be Johnson's 14 such as some of the particle sizes that are 14 baby powder or SHOWER TO SHOWER®, correct? 15 15 used in the pleurodesis products, are more A. Yes. 16 Q. All right. 16 likely to initiate an acute inflammatory 17 response due to the fact that they're large A. Or Shimmer. I think that's the 17 enough that the body will recognize them with 18 other name. There's a third product. 18 19 a fairly robust foreign body response. Q. Okay. But my question to you 19 is, you actually cite a number of pieces of 20 What is your definition of 20 literature in the section about the alleged 21 large? 21 22 So the literature varies, but 22 toxicity of talc that don't relate to the 23 certainly particles that are above -- some of 23 overall consumer products at issue in this 24 24 the literature talks about particles that are case, correct? 25 in the range of 25 to 75. Some of them talk 25 MS. PARFITT: Objection. Form. Page 127 Page 129 1 about larger particles even than that. 1 THE WITNESS: No, I would 2 disagree with that when you use the 2 It has to do with the fact 3 word "relate." Relate to me means is 3 that -- this is complicated by the fact that 4 it relevant to the assessment, and 4 any consumer product -- or any talc sample 5 5 they are, even if they're not just on will have a range of sizes because they don't 6 the finished product. 6 select for one size. They select for smaller 7 But if what you mean is that 7 than. So a 200 mesh, a 400 mesh, that has do 8 there are studies that did not test 8 with what will filter through. 9 the consumer product but individual 9 So pleurodesis, they try to 10 ingredients or -- that is true, yes, 10 avoid for those products the really small --11 but all of that is relevant or relates large amounts of less than 10 because that 11 12 to the overall risk assessment. 12 leads to respiratory distress, whereas many 13 QUESTIONS BY MS. BRANSCOME: 13 of the consumer talc products are using much 14 Q. Okay. So given your view that smaller, finer particles to get that feel and 14 15 information about the individual constituents performance they want from the consumer body 15 16 is relevant to evaluating the overall 16 powders. 17 toxicity of the ultimate consumer products, Q. Have you reviewed -- focusing 17 18 then my question to you is: How does the specific on Johnson & Johnson's products, 18 19 structure and size of the component talc 19 have you reviewed the documents that relate 20 particles play a role in toxicity with 20 to the specifications for the Johnson's 21 respect to ovarian cancer? products with respect to the size of the 21 22 A. Just generally -- it's not 22 plate particles? 2.3 just -- well, with respect to ovarian cancer, 23 A. I have seen those, yes. I we start with irritation, inflammation 24 24 can't tell you what each of them says without 25 potential. Size of particles and shape are pulling them out, but, yes, that is certainly 25

Page 130 Page 132 1 documents I have seen and relied upon. 1 effects that beneficiation can have on the 2 Q. Is it consistent with your 2 level of the component -- the components in 3 understanding that it was Johnson & Johnson's 3 talc and what ultimately ends up in one of 4 intention to select large platy talc Johnson & Johnson's consumer products? 4 5 5 particles for its products? MR. MEADOWS: Objection. 6 6 MS. PARFITT: Objection to THE WITNESS: So I'm not -- I'm 7 7 form. not familiar with all the details, but 8 QUESTIONS BY MS. BRANSCOME: 8 I am familiar that it is a process 9 Q. Have you seen that in the 9 they're using to attempt to result in 10 10 a product that has characteristics documents? that would be desirable for a consumer 11 A. I don't know that it's 11 12 described quite that way, but they certainly 12 product. 13 were doing a 200 mesh selection. So -- for 13 Again, there is my their body powders products. So -- and they 14 14 understanding that others are going to were trying -- and they did make attempts to 15 15 be discussing the geology or the 16 look for sources that were more platy talc 16 processing, and that is not something 17 than other forms, but that doesn't ensure 17 I'm looking at. 18 18 that everything is platy talc. The literature as it relates to 19 Q. Are you familiar with the term 19 what has been tested in the public 20 "fines"? 20 literature in particular, and that 21 A. Yes, generally, but I'm not --21 would be either an ingredient or a --22 but I'm not an expert in the processing of 2.2 or a consumer product or a -- they may talc as far as how you would go about discuss exposure occupationally to 23 23 choosing an ore or a mine. There's others 24 24 mining or milling, which is -- which that will be addressing that. That's not my 25 is an issue that you can consider when 25 Page 131 Page 133 1 area. 1 you're reviewing that literature as 2 What is your understanding of 2 well. 3 the term "fines"? 3 **OUESTIONS BY MS. BRANSCOME:** A. My understanding of the term 4 Q. Okay. And so when you cite --4 5 5 "fines" has to be looking for a sample or a for example, you have a significant number group that has been processed such that it 6 of -- I'm trying to find the right paragraph. 6 7 7 You have a section in your has certain characteristics. 8 Other than that, I would refer 8 report where you discuss a number of 9 9 you to the individuals in litigation that are different articles that relate to talc, and 10 going to be dealing with the processing. 10 in parentheses you identify that the talc 11 Q. Okay. Have you taken into 11 source might be cosmetic, it might be account in your analysis in any way the 12 industrial, things of that nature, correct? 12 beneficiation process that occurs between the 13 Yes, I do that on purpose 13 time that the talc is mined and it ends up in 14 because I wanted -- I did look at the 14 15 15 literature to understand what they were -one of the consumer products that is relevant 16 to your analysis? 16 what they were -- what type of exposure they 17 MR. MEADOWS: Objection. 17 were describing. 18 THE WITNESS: So what do you 18 Q. Okay. And so understanding 19 mean by taking it into account? Am I 19 that some of those products are not aware that they have something that's 20 representative of what ultimately is in 20 Johnson's baby powder, do you have anything 21 in place for that? Yes. 21 22 in your report that explains how you did or But take into account, what do 22 23 did not give weight to those particular 23 you mean by that? 24 QUESTIONS BY MS. BRANSCOME: 24 studies? 25 Q. Are you familiar with the 25 MS. PARFITT: Objection. Form.

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1	THE WITNESS: Let me look and	1	something that ever ended up in Johnson's
2	see what I say.	2	products, correct?
3	If the question has to do with	3	MR. MEADOWS: Objection.
4	numerical rankings, no, I did not do	4	THE WITNESS: I don't think I
5	that. But you're asking something	5	can answer that yes or no. I haven't
6	else, right, broader than that,	6	done an assessment to see whether it
7	correct?	7	ever ended up in the products. That's
8	QUESTIONS BY MS. BRANSCOME:	8	a different question.
9	Q. The question that I have is,	9	I certainly am aware of the
10	how did is there somewhere in this report	10	fact that was not a primary source of
11	that I can understand the weight that you	11	their tale, that is true. I do know
12	assigned to say a study that related to	12	that.
13	industrial tale as opposed to information	13	In other words, I don't have
14	about cosmetic talc, for example?	14	records from going back from 1894
15	MR. MEADOWS: Objection.	15	on what the source of their talc was.
16	THE WITNESS: So I I'm I	16	So I can't tell you over time.
17	believe I address that. I don't know	17	What I do know, what's been put
18	it's exactly answering your question,	18	into depositions and testimony of
19	but I lay out for you the	19	company employees more recently, where
20	characteristics of the literature in	20	it's my understanding that the
21	paragraph 37, and I point out that the	21	principal sources over the years were
22	scientific literature varies.	22	either the Vermont mine, the Italian
23	And the fact and I point	23	mine or the Chinese mine. And there
24	and I admit I'm not admitting. I'm	24	were different interruptions in time
25	stating the fact that in some cases	25	where different mines were used,
	Page 135		Page 137
1	the authors will not describe it	1	Page 137 depending on sourcing.
1 2		1 2	
1 2 3	the authors will not describe it		depending on sourcing.
1 2 3 4	the authors will not describe it specifically as the type of tale, but	2	depending on sourcing. QUESTIONS BY MS. BRANSCOME:
1 2 3 4 5	the authors will not describe it specifically as the type of talc, but just talc, whereas with no description of purity or state, for example. But in cases where the	2	depending on sourcing. QUESTIONS BY MS. BRANSCOME: Q. So as part of your expert
1 2 3 4 5	the authors will not describe it specifically as the type of talc, but just talc, whereas with no description of purity or state, for example. But in cases where the literature does, I did consider that	2 3 4 5 6	depending on sourcing. QUESTIONS BY MS. BRANSCOME: Q. So as part of your expert analysis where you are evaluating articles that relate to different types of talc from different sources of talc, have you done an
1 2 3 4 5 6	the authors will not describe it specifically as the type of talc, but just talc, whereas with no description of purity or state, for example. But in cases where the literature does, I did consider that in my weight of the evidence.	2 3 4 5 6 7	depending on sourcing. QUESTIONS BY MS. BRANSCOME: Q. So as part of your expert analysis where you are evaluating articles that relate to different types of talc from different sources of talc, have you done an analysis of how those particular types of
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Page 138 Page 140 1 So I am -- I am certainly 1 that to draw conclusions based upon 2 recognizing, and I analyzed on the 2 what was available for me to assess. 3 paper -- through the papers what type 3 QUESTIONS BY MS. BRANSCOME: of product, if available, that the 4 4 Q. Okay. 5 5 data is on. I don't know how else to answer A. 6 it for you. That's what the section is meant 6 But if you read my report in 7 7 the process of risk assessment, all of to do, and that's why I broke it out that 8 these categories of papers are 8 way. You know, I recognize that there is 9 relevant to telling you something 9 data on different things. 10 What's interesting about even 10 about what talc can do. And then when the data on different things, there's a 11 you talk about drawing final 11 12 12 common mechanism that is involved with the conclusions, I'm looking for information, if I can, and I have it, 13 13 type of tissue toxicity you get, and that's 14 that is on point to the product that 14 irritation and inflammation. Regardless of 15 15 whether it is of a certain grade or not, you was sold. 16 16 get certain types of adverse reactions. May So certainly the studies that 17 give me information on cosmetic-grade 17 be a more sustained reaction with a 18 18 talc are extremely important to my industrial grade versus cosmetic grade, but 19 assessment, and they're ones that I've 19 they all have the capability to produce that discussed or we've even used in trial 20 type of adverse effect. 20 21 before when we've talked about putting 21 Q. Dr. Plunkett, where can you 2.2 point me to in your report that you discuss 22 together a timeline. 23 the weight that you give studies that relate 23 That's what this is about, by 24 the way. This discussion here, I'm 24 to talc from New York as opposed to studies starting to lay out what information 25 that relate to cosmetic talc that ultimately 25 Page 139 Page 141 1 was available over time, and that's 1 ended up in Johnson's baby powder? 2 simply what this is. It's a survey of 2 MS. PARFITT: Objection. Form. 3 the literature that talks about 3 THE WITNESS: I've tried to 4 4 adverse effects of talc, and if I can, answer that for you. The weight that 5 I separate it into different qualities 5 I'm giving -- the weight that I'm б 6 giving is part of my assessment. So, or purities. 7 7 **OUESTIONS BY MS. BRANSCOME:** again, I don't give numerical 8 8 rankings. I've answered that for you. Q. Dr. Plunkett, respectfully, I 9 don't believe you answered my question. 9 I don't do that. 10 Can you point me to anywhere in 10 What I instead do is I'm 11 your expert report that's been produced in 11 looking at everything that's relevant, 12 12 this MDL where you do an analysis of how the everything that's available. I do different talc types and sources that you are 13 categorize it, so I am selecting -- I 13 am identifying or analyzing the 14 citing as support for the toxicity of talc 14 information for what it describes. 15 generally relate to the products manufactured 15 16 by Johnson & Johnson? 16 And then if you go further on down, I MR. MEADOWS: Objection. 17 try to tell you what I think is 17 18 important about that information. 18 THE WITNESS: So I don't know 19 The overall conclusions I'm 19 how else to answer that but to tell 20 drawing in the report, though, when I 20 you I think that's what this whole 21 cite to specific studies in the risk 21 section is about. I step you 22 assessment, the majority of those 22 through -- I identify different types studies I believe that I'm citing for 23 of evidence. I identify for you what 23 was tested in those different pieces 24 you, outside of notice, have to do 24 25 with -- that's more of a warnings of evidence, and then I step through 25

36 (Pages 138 to 141)

1 2	Page 142 issue have to do with the issue of		Page 144
	issue have to do with the issue of		
2	issue nave to do with the issue of	1	QUESTIONS BY MS. BRANSCOME:
	cosmetic talc. Because the human	2	Q. I was simply asking: Did you
3	studies are describing cosmetic talc.	3	do an analysis that would allow you to
4	The NTP studies is a pure talc. Many	4	compare the ingredients in another product,
5	of the in vitro studies and other	5	like consumer Cashmere Bouquet, before you
6	animal studies are looking at,	6	rendered an opinion with respect to Johnson's
7	quote/unquote, a talc that is not an	7	baby powder based on tests of Cashmere
8	industrial grade or from a mine that	8	Bouquet? Did you do that analysis?
9	would have be looked at in that	9	MR. MEADOWS: Objection.
10	way. So	10	THE WITNESS: I do not have
	UESTIONS BY MS. BRANSCOME:	11	access to internal company documents
12	Q. You understand that there are	12	for the manufacturers of Cashmere
	ifferent types of cosmetic talc, correct?	13	Bouquet, so I certainly couldn't do
14	A. Yes, I am aware.	14	the analysis in the same way that I
15	Q. And cosmetic talc can be mined	15	can do it here, where I can identify
	om a number of different mines globally,	16	what Johnson & Johnson and Imerys
	orrect?	17	describe as sources of the talc that
18	A. That's correct.	18	was used for the Johnson & Johnson
19	Q. And some of the studies that	19	baby powder, without
	ou cite in your report are testing cosmetic	20 21	QUESTIONS BY MS. BRANSCOME:
	lle from other consumer products, for	22	Q. So you have no way of knowing
23	xample, Cashmere Bouquet, correct?	23	one way or the other whether that talc is
	A. Some. The majority of them are	24	similar, correct? MR. MEADOWS: Objection.
24 no	ot, but I would agree that some do, yes. Q. Okay. Have you done an	25	MS. PARFITT: Objection.
23	Q. Okay. Have you done an	23	MS. I ARITIT. Objection.
	Page 143		Page 145
1 an	alysis of how the talc that is used in	1	THE WITNESS: Well, I think I
	ashmere Bouquet, for example, relates to the	2	do know it's similar, if you look on
	c that is used in Johnson's baby powder?	3	the bottle as far as what is described
4	Is that an analysis that you	4	it being, but if you're asking me
5 ha	ve done before relying on that information	5	if you're asking did we fingerprint it
6 in	your report?	6	to only a particular mine, this is the
7	MR. MEADOWS: Objection.	7	beauty of the data. The data shows
8	MS. PARFITT: Objection.	8	that regardless of the type of product
9	THE WITNESS: My analysis I	9	you're looking at, there's consistency
10	did do an analysis to look at what was	10	across the study.
11	described, what products are	11	So but I did not try to
12	described, but I certainly I	12	segregate out studies that only dealt
13	certainly did not throw out studies	13	with Cashmere Bouquet, no, I did not
14	that described Cashmere Bouquet	14	do that.
15	because I would I still believe as	15	QUESTIONS BY MS. BRANSCOME:
16	a toxicologist and a risk assessor	16	Q. Okay. As you sit here today as
17	that those types of products are	17	a toxicologist, is it your position that
18	important to the overall weight of the	18	industrial-grade talc that might contain up
19	evidence about the hazard and the	19	to 70 percent tremolite presents the same
20	risks posed by talc.	20	level of toxic effect as cosmetic talc that
21	You know, I just I just I	21	may contain no tremolite or tremolite at a
22	guess I disagree with you if you're	22	very, very low level?
23	saying they're irrelevant. I don't	23	MS. PARFITT: Objection. Form.
2.4			
24 25	believe that they are.	24 25	THE WITNESS: I haven't formed that opinion, no.

Page 146 Page 148 1 QUESTIONS BY MS. BRANSCOME: 1 identified characteristics. 2 Q. Okay. And so have you formed 2 There's -- within the 3 an opinion that I could find in your report 3 asbestos -- the asbestos literature that discusses in any way the relative 4 there's -- it's one of the forms -- forms of 4 toxicity of different types of talc? 5 5 asbestos that's described. For example, in A. That, you may find. I need to 6 6 IARC, they describe all of the ones that have 7 go back and look how I set it out, but I 7 carcinogenic properties. It's one of them. think I -- I talked with you about the 8 8 Within the literature within 9 difference between fibrous versus platy. I 9 Johnson & Johnson's documents, there's 10 10 tremolite discussed as -- I assume them do discuss that. And I talk about the problems referring to asbestos tremolite, asbestos in 11 11 12 when you have a complex mixture that has 12 a tremolite characteristic. I have seen 13 added to it things like asbestos and heavy 13 tremolite talc also mentioned in the metals, because I talk about the additivity 14 14 literature. 15 issue that can come to play. So that -- in 15 If you want a specific 16 other words, increased risk when you have a 16 discussion of each of those, again, complex mixture with additional components there's -- I understand there's experts that 17 17 are going to describe the distinguishing that all share the same toxic properties as 18 18 far as target organs or types of effects or 19 characteristics of each of those. 19 mechanisms that are triggered in the body. 20 20 I'm only setting out this is 21 That's what I point you to. 21 what I have seen, talked about, in the 2.2 I -- I don't -- that's the only 2.2 literature. 23 way I can answer that for you, I think, based 23 So you are not an expert on the O. 24 on what I know I have in here. 24 differences between fibrous talc, asbestiform 25 Q. Okay. You talk about the term 25 talc, non-asbestiform talc and tremolite as Page 147 Page 149 "asbestiform talc." it relates to toxicity. Is that your opinion 1 1 2 You talk about asbestiform 2 today? 3 talc. 3 A. No, that's not what I'm saying. 4 4 I'm saying that if you want me to -- I'm --Are you familiar with that? 5 5 A. I do mention that in my report, if you want me to describe the 6 6 characteristics and the morphology of each of yes. 7 7 those individually, that's something a Where are you? 8 8 Q. At paragraph 30. It's on geologist would do. 9 page 19 of your report. 9 But certainly as far as the A. Yes, I'm here. 10 10 toxicity assessment I did, each of these 11 Okay. And the first sentence 11 types of -- each of these words, I guess, or in paragraph 30 you state, "In the published 12 names have been applied in the literature 12 medical literature, there is often discussion when they talk about toxicity of talc. Some 13 13 14 of talc using terms such as fibrous talc, 14 of the literature talks about fibrous talc or asbestiform talc, non-asbestiform talc or 15 15 just -- other literature just talks about 16 tremolite." 16 talc. Some of it, for example, the IARC 17 Do you see that? 17 monographs, distinguish between asbestiform 18 A. Yes, I do. 18 talc and non-asbestiform talc in their 19 Q. Okay. Is it your opinion that 19 assessments of the cancer risk. 20 tremolite is a form of talc? 20 And then tremolite is discussed 21 A. So tremolite is a -- is a -- is 21 as a component of talc. And I have seen papers that talk about tremolite --22 a type of fiber or a -- tremolite is a -- is 22 23 a substance or a entity that has been 23 nontremolite talc or tremolite-containing talc. That's how you most often see it. 24 identified as a specific morphology, I guess, 24 25 identified characteristics of a -- it has 25 So it's the idea that it is a

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constituent of certain mines that -- and that's my understanding of it. But if you want -- and they all -- they all certainly do show that the toxicity can be affected, whether it's a fiber or a platy particle. So tremolite being a fiber would certainly affect my overall assessment of risk. The more tremolite that you would have would make -- would make it more likely to be reactive in terms of a foreign body response, depending on the size.

2.2

Q. What's your basis for saying that?

A. That's based on a fibrous form versus a platy particle form. That's the issue of -- I have that paragraph where I talk about what macrophages look for, can engulf or not engulf. So those are all things that are important to a toxicologist to understand exist.

But certainly within my assessment I have to include literature from all of those because of the fact that all of those are relevant to the toxicity profile, since I know that the cosmetic baby powders Page 152

- Q. Okay. And so when you're looking at a complex mixture, you would agree as a toxicologist it would be important to understand the constituent elements of that mixture, correct?
 - A. Yes, it is important to understand that this is -- what is in the mixture, and that's -- that's part of what I try to do.
 - Q. Okay. And it would be important before drawing conclusions from one study that might have different constituent components, it's important to understand the relative toxicity of individual constituent elements, correct?
 - A. Depends if you can or not. I mean, there's certain types of studies you can, where in the published literature that's been described. That's why I'm pointing this out. It's the idea that within the literature, when you go through, it's important to understand what you can say about the consistency across the literature where maybe different types of talc are discussed.

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and the data I've seen shows detection of something called fibrous talc.

I see detection of tremolite within certain samples of baby powder.

And then I have just the general category of asbestiform versus non-asbestiform when I consider the way, for example, IARC has reviewed the carcinogenicity.

So those are -- those are terms that I'm laying out because I think they are something you need to understand exists in the literature.

Q. Okay. But I'm trying to understand, not helping me understand the literature. I'm trying to understand your opinions with respect to toxicity.

Is it, for example, your opinion that fibrous talc has the same toxic potential -- let's focus specifically with respect to ovarian cancer -- as tremolite?

A. I haven't formed that opinion, but, again, I would -- my opinion has been formed on the fact that we have complex mixture that includes all of these things.

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And that's what I -- I think I lay out for you. I tell you there's consistency in certain toxic effects that are seen. Regardless of the form that you're looking at, talc has certain properties, and all of these things are -- been shown to be in the complex mixture, so I have -- as a result, all of that literature has relevance to at least the hazard part of my assessment, and certainly have relevance to -- when you want to talk about warning and the final risk assessment, they're definitely relevant, but certainly the -- when I go through this process, I am trying to focus as much as I can on a product that is most similar to the one I'm assessing.

So obviously that's why -that's one of the reasons I do look at the human data, because the human data is involving a consumer product use, which is what I'm talking about here.

- Q. Is it using specifically Johnson's baby powder?
 - A. Many of them are, yes.
 - Q. Okay.

39 (Pages 150 to 153)

	Page 154		Page 156
1	A. Based on my understanding of	1	across the studies that are dealing
2	what I see discussed within the literature.	2	with not the consumer product but
3	Q. Did you identify in your report	3	other descriptions, there is a
4	specifically which report which studies	4	consistency in the types of effects
5	have used a consumer product manufactured by	5	you see.
6	Johnson & Johnson?	6	And since I'm not quantifying
7	A. I haven't laid them out	7	the risk but identifying it as being
8	individually, no, but I am aware of	8	increased or not, in other words, is
9	discussions of this general issue within some	9	it more likely than not that someone
10	of the documents I've seen, and essentially	10	exposed in this way could be at a risk
11	Johnson's body powders products were the	11	of ovarian cancer, that's what I'm
12	overwhelming share of the market.	12	talking about.
13	Q. But you would agree that	13	So again, it's if I was
14	studies that did not involve the consumer	14	trying to identify differences in
15	product manufactured by Johnson & Johnson	15	cancer potency factors for different
16	should be given less weight when analyzing	16	types, then, yes, if I had an animal
17	whether or not there are risks associated	17	study on each of those, I could
18	specifically with Johnson & Johnson's	18	compare potency for cancer, but that
19	products?	19	hasn't been done.
20	MS. PARFITT: Objection. Form.	20	QUESTIONS BY MS. BRANSCOME:
21	MR. MEADOWS: Objection.	21	Q. Okay.
22	THE WITNESS: It depends on the	22	A. So instead, what I have to do
23	question being asked within the	23	is rely on what is available to me. And
24	assessment, the risk assessment. It	24	based on my judgment, that's how I review the
25	really does, I mean, because each of	25	studies.
	Page 155		Page 157
1	these studies brings a piece of	1	O A las for the collins of at
		1 +	Q. And so for the opinions that
2		2	
2	evidence to the risk assessment.		you are offering in the MDL, you agree that you are not quantifying the risk associated
	evidence to the risk assessment. And so the question is for	2	you are offering in the MDL, you agree that
3	evidence to the risk assessment. And so the question is for each one, you consider it on a	2	you are offering in the MDL, you agree that you are not quantifying the risk associated
3 4	evidence to the risk assessment. And so the question is for each one, you consider it on a case-by-case basis. It is possible,	2 3 4	you are offering in the MDL, you agree that you are not quantifying the risk associated with Johnson's baby powder, SHOWER TO SHOWER®
3 4 5	evidence to the risk assessment. And so the question is for each one, you consider it on a case-by-case basis. It is possible, yes, that you would give less weight.	2 3 4 5	you are offering in the MDL, you agree that you are not quantifying the risk associated with Johnson's baby powder, SHOWER TO SHOWER® or Shimmer with respect to the potential for
3 4 5 6	evidence to the risk assessment. And so the question is for each one, you consider it on a case-by-case basis. It is possible, yes, that you would give less weight. It's also possible that you would not,	2 3 4 5 6	you are offering in the MDL, you agree that you are not quantifying the risk associated with Johnson's baby powder, SHOWER TO SHOWER® or Shimmer with respect to the potential for causing ovarian cancer?
3 4 5 6 7	evidence to the risk assessment. And so the question is for each one, you consider it on a case-by-case basis. It is possible, yes, that you would give less weight.	2 3 4 5 6 7	you are offering in the MDL, you agree that you are not quantifying the risk associated with Johnson's baby powder, SHOWER TO SHOWER® or Shimmer with respect to the potential for causing ovarian cancer? MS. PARFITT: Objection. Form.
3 4 5 6 7 8	evidence to the risk assessment. And so the question is for each one, you consider it on a case-by-case basis. It is possible, yes, that you would give less weight. It's also possible that you would not, dependent upon what you know about	2 3 4 5 6 7 8	you are offering in the MDL, you agree that you are not quantifying the risk associated with Johnson's baby powder, SHOWER TO SHOWER® or Shimmer with respect to the potential for causing ovarian cancer? MS. PARFITT: Objection. Form. THE WITNESS: In terms of a
3 4 5 6 7 8 9	evidence to the risk assessment. And so the question is for each one, you consider it on a case-by-case basis. It is possible, yes, that you would give less weight. It's also possible that you would not, dependent upon what you know about that study and how it relates to other	2 3 4 5 6 7 8	you are offering in the MDL, you agree that you are not quantifying the risk associated with Johnson's baby powder, SHOWER TO SHOWER® or Shimmer with respect to the potential for causing ovarian cancer? MS. PARFITT: Objection. Form. THE WITNESS: In terms of a cancer potency factor, that is true, I
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3 4 5 6 7 8 9 10	evidence to the risk assessment. And so the question is for each one, you consider it on a case-by-case basis. It is possible, yes, that you would give less weight. It's also possible that you would not, dependent upon what you know about that study and how it relates to other studies that are out there. QUESTIONS BY MS. BRANSCOME:	2 3 4 5 6 7 8 9 10	you are offering in the MDL, you agree that you are not quantifying the risk associated with Johnson's baby powder, SHOWER TO SHOWER® or Shimmer with respect to the potential for causing ovarian cancer? MS. PARFITT: Objection. Form. THE WITNESS: In terms of a cancer potency factor, that is true, I am not. Instead, what I am doing is I am quantifying whether or not I
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3 4 5 6 7 8 9 10 11 12 13	evidence to the risk assessment. And so the question is for each one, you consider it on a case-by-case basis. It is possible, yes, that you would give less weight. It's also possible that you would not, dependent upon what you know about that study and how it relates to other studies that are out there. QUESTIONS BY MS. BRANSCOME: Q. So methodologically, how would I understand from your report marked as	2 3 4 5 6 7 8 9 10 11 12 13	you are offering in the MDL, you agree that you are not quantifying the risk associated with Johnson's baby powder, SHOWER TO SHOWER® or Shimmer with respect to the potential for causing ovarian cancer? MS. PARFITT: Objection. Form. THE WITNESS: In terms of a cancer potency factor, that is true, I am not. Instead, what I am doing is I am quantifying whether or not I believe that the risk is increased above a background risk.
3 4 5 6 7 8 9 10 11 12 13	evidence to the risk assessment. And so the question is for each one, you consider it on a case-by-case basis. It is possible, yes, that you would give less weight. It's also possible that you would not, dependent upon what you know about that study and how it relates to other studies that are out there. QUESTIONS BY MS. BRANSCOME: Q. So methodologically, how would I understand from your report marked as Exhibit 4 under what circumstances to give a	2 3 4 5 6 7 8 9 10 11 12 13 14	you are offering in the MDL, you agree that you are not quantifying the risk associated with Johnson's baby powder, SHOWER TO SHOWER® or Shimmer with respect to the potential for causing ovarian cancer? MS. PARFITT: Objection. Form. THE WITNESS: In terms of a cancer potency factor, that is true, I am not. Instead, what I am doing is I am quantifying whether or not I believe that the risk is increased above a background risk. That has to do with that's
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3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	evidence to the risk assessment. And so the question is for each one, you consider it on a case-by-case basis. It is possible, yes, that you would give less weight. It's also possible that you would not, dependent upon what you know about that study and how it relates to other studies that are out there. QUESTIONS BY MS. BRANSCOME: Q. So methodologically, how would I understand from your report marked as Exhibit 4 under what circumstances to give a study that relates to, for example, industrial talc less weight than a study that actually used Johnson's baby powder? MR. MEADOWS: Objection.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	you are offering in the MDL, you agree that you are not quantifying the risk associated with Johnson's baby powder, SHOWER TO SHOWER® or Shimmer with respect to the potential for causing ovarian cancer? MS. PARFITT: Objection. Form. THE WITNESS: In terms of a cancer potency factor, that is true, I am not. Instead, what I am doing is I am quantifying whether or not I believe that the risk is increased above a background risk. That has to do with that's where I bring in, in my risk assessment, the human data, because the human data is showing statistically significant increases in
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3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	evidence to the risk assessment. And so the question is for each one, you consider it on a case-by-case basis. It is possible, yes, that you would give less weight. It's also possible that you would not, dependent upon what you know about that study and how it relates to other studies that are out there. QUESTIONS BY MS. BRANSCOME: Q. So methodologically, how would I understand from your report marked as Exhibit 4 under what circumstances to give a study that relates to, for example, industrial talc less weight than a study that actually used Johnson's baby powder? MR. MEADOWS: Objection. THE WITNESS: Well, I've tried to tell you that. That's what I said	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	you are offering in the MDL, you agree that you are not quantifying the risk associated with Johnson's baby powder, SHOWER TO SHOWER® or Shimmer with respect to the potential for causing ovarian cancer? MS. PARFITT: Objection. Form. THE WITNESS: In terms of a cancer potency factor, that is true, I am not. Instead, what I am doing is I am quantifying whether or not I believe that the risk is increased above a background risk. That has to do with that's where I bring in, in my risk assessment, the human data, because the human data is showing statistically significant increases in risk in populations using the consumer product.
3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	evidence to the risk assessment. And so the question is for each one, you consider it on a case-by-case basis. It is possible, yes, that you would give less weight. It's also possible that you would not, dependent upon what you know about that study and how it relates to other studies that are out there. QUESTIONS BY MS. BRANSCOME: Q. So methodologically, how would I understand from your report marked as Exhibit 4 under what circumstances to give a study that relates to, for example, industrial talc less weight than a study that actually used Johnson's baby powder? MR. MEADOWS: Objection. THE WITNESS: Well, I've tried to tell you that. That's what I said for you. That's why I am doing it. I	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	you are offering in the MDL, you agree that you are not quantifying the risk associated with Johnson's baby powder, SHOWER TO SHOWER® or Shimmer with respect to the potential for causing ovarian cancer? MS. PARFITT: Objection. Form. THE WITNESS: In terms of a cancer potency factor, that is true, I am not. Instead, what I am doing is I am quantifying whether or not I believe that the risk is increased above a background risk. That has to do with that's where I bring in, in my risk assessment, the human data, because the human data is showing statistically significant increases in risk in populations using the consumer product. So I have a quantification
3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	evidence to the risk assessment. And so the question is for each one, you consider it on a case-by-case basis. It is possible, yes, that you would give less weight. It's also possible that you would not, dependent upon what you know about that study and how it relates to other studies that are out there. QUESTIONS BY MS. BRANSCOME: Q. So methodologically, how would I understand from your report marked as Exhibit 4 under what circumstances to give a study that relates to, for example, industrial talc less weight than a study that actually used Johnson's baby powder? MR. MEADOWS: Objection. THE WITNESS: Well, I've tried to tell you that. That's what I said for you. That's why I am doing it. I certainly am trying to focus in on	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	you are offering in the MDL, you agree that you are not quantifying the risk associated with Johnson's baby powder, SHOWER TO SHOWER® or Shimmer with respect to the potential for causing ovarian cancer? MS. PARFITT: Objection. Form. THE WITNESS: In terms of a cancer potency factor, that is true, I am not. Instead, what I am doing is I am quantifying whether or not I believe that the risk is increased above a background risk. That has to do with that's where I bring in, in my risk assessment, the human data, because the human data is showing statistically significant increases in risk in populations using the consumer product. So I have a quantification where I'm using the word "increased,"

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Page 158 Page 160 1 in that way, but I'm not giving it a 1 QUESTIONS BY MS. BRANSCOME: 2 number. I'm not saying that the 2 Q. In reaching your opinion in the 3 cancer potency factor is such that you 3 MDL that there is an increased risk above 4 4 increase the risk from one in a background of ovarian cancer from the use of 5 5 million to 10 in a million to 1 in a products manufactured by Johnson & Johnson, б 6 thousand. That I have not done have you made an attempt to identify 7 7 because I don't have the data, the specifically which studies, the human studies 8 studies. The company has not done 8 on which you rely, test or look at people who 9 studies on each of these to allow me 9 have used Johnson & Johnson's products? 10 10 MS. PARFITT: Objection. Form. to do that. 11 **OUESTIONS BY MS. BRANSCOME:** 11 THE WITNESS: It's my -- my 12 Q. Okay. The reference that you 12 review of the study indicates that I 13 made to the human data that you believe shows 13 would say for the vast majority of a statistically increased risk in populations 14 14 them you cannot do that. 15 using the consumer product, have -- which --15 But you can take what is 16 have you identified in your report which of 16 reported and look at things such as 17 those studies are specifically using a 17 market share and those kind of things product that was manufactured by Johnson & to get an idea of what you believe the 18 18 19 Johnson? 19 exposure would have been. 20 20 But certainly I have not -- I A. I don't lay that out for my 21 report, I do not, but certainly it is 21 have not tried to apply some kind of a 22 something that for some of the studies I 22 numerical value to how many people in believe you can -- you might be able to get the study may have used Johnson's baby 23 23 24 some of that information from. But certainly 24 powder or not, no, that has not been 25 25 I have not laid that out individually in my done. I don't think anybody -- any of Page 159 Page 161 1 1 report, no. the bodies that have looked at this 2 Q. And you would agree that for 2 have done that. 3 some of those studies there is no information 3 **QUESTIONS BY MS. BRANSCOME:** 4 as to the specific type of consumer talc that 4 Q. You have not done a market 5 5 the individuals who are being studied used, share analysis, correct? 6 6 A. No, I've seen this in documents correct? 7 7 MS. PARFITT: Objection. Form. only. I have not done my own. There are 8 THE WITNESS: I would agree 8 company documents that talk about their 9 that in some of those studies they're 9 market share. 10 not saying, but that is why you look 10 Q. Okay. Have you made an attempt 11 at the evidence overall. 11 to examine the levels of fibrous talc or 12 And what's important to look at 12 asbestiform talc that are in different 13 in terms of now -- if you wanted to go 13 consumer products, aside from Johnson's baby to Bradford Hill, that's why you look 14 14 powder or SHOWER TO SHOWER® or Shimmer? 15 at things such as consistency. So 15 A. So for that are you referring 16 what do the studies show. We see a 16 to things such as -- other types of cosmetics 17 certain level of increased risk across 17 like foundations or lipsticks or --18 studies, regardless of who did the 18 Q. I'll rephrase. 19 study or what population was being 19 Have you made any attempt to 20 looked at. 20 examine whether other cosmetic talc body 21 So that's the best way I can 21 powders have a different percentage of 22 answer that for you. That is -- that 22 fibrous, or what you refer to as asbestiform is part of the -- of the assessment 23 23 talc, from the Johnson & Johnson products? 24 that you look at. 24 Have you done any analysis to 25 25 make that comparison one way or the other?

41 (Pages 158 to 161)

	Page 162		Page 164
1	MS. PARFITT: Objection. Form.	1	that I state for you that it's my
2	THE WITNESS: I certainly	2	opinion that Cashmere Bouquet has this
3	haven't done I certainly didn't do	3	specific pattern of constituents as
4	a directed analysis to try to	4	compared to Johnson & Johnson's. No,
5	determine that, but there is	5	I have not done that.
6	information, I believe, in I think	6	QUESTIONS BY MS. BRANSCOME:
7	if you look at some of Dr. Longo's	7	Q. Okay. And that would be true
8	work, that may be there.	8	for any other brand of cosmetic talc, body
9	And I believe in Dr. Blount's	9	powders, Jean Nate, Lily of the Valley, not
10	published paper there may be a	10	just Cashmere Bouquet, correct?
11	discussion of the type of powder	11	MS. PARFITT: Objection.
12	product used, where she was looking	12	THE WITNESS: That is correct,
13	for at least for asbestiform	13	I don't have access to that
14	asbestos within the talc. It may be	14	information.
15	tremolite as well, but if you want	15	QUESTIONS BY MS. BRANSCOME:
16	me to look, I can do that. I just	16	Q. Have you done any analysis of
17	don't recall whether I think she	17	the constituent components of talc and how
18	did talk about sources of the talc,	18	they have changed even within Johnson's
19	where it came from, so	19	Johnson & Johnson's manufactured products,
20	QUESTIONS BY MS. BRANSCOME:	20	how the constituents of the consumer products
21	Q. Okay. But as you sit here	21	may or may not have changed over time?
22	today, you can't point me to any analysis	22	A. I've done some of that, yes,
23	that you did or an analysis that you relied	23	and I laid that out, I think, for you, when I
24	on that would relate different brands of	24	talk about the differences in the products
25	cosmetic talc body powders with respect to	25	that are described within the documents, the
-		_	
1	their constituent components?	1	company documents, from the '70s versus the
2	MS. PARFITT: Objection.	2	'80s versus later on, as far as the changes
3	Completely misstates her testimony.	3	that were made to specifications of the
4 5	She mentioned Dr. Blount. She mentioned others.	4 5	product, for example. That's something
6	THE WITNESS: So I think what I	6	and I think I've talked about that a bit at trial as well.
7		7	
8	started with, I said I haven't done a	8	Q. Okay. And is it your view that the risk potential for Johnson & Johnson's
O	directed analysis to try to determine	9	•
9 10	specifically how this product versus this product versus this product may	10	manufactured products have changed at all over time with respect to ovarian cancer?
11	have looked over time, because I don't	11	MS. PARFITT: Objection.
12	have access to a full data to do that.	12	THE WITNESS: I have not I
13	But what I do have is data that	13	have not attempted to differentiate a
13 14	has I do see published data, for	14	risk potential at only one point in
15	example, Blount and maybe some of the	15	time.
16	other published studies, that looked	16	
17	at this issue, at least of asbestos	17	What I have done over points of time is looked at the issue of
18	presence in talc. And I believe	18	warnings and what should be warned
19	Dr. Longo also had things that weren't	19	about.
20	just Johnson's. I believe he had	20	But my analysis related to the
21	Cashmere Bouquet, for example, samples	21	hazard or the risk assessment of the
22	in some of the things he looked at.	22	products is considering all of the
23	So I can point you to those	23	available information, which would be
د ت			all of that information over time.
24	things that I have reviewed but I	1 /4	
24 25	things that I have reviewed, but I haven't there's nowhere in here	24 25	an of that information over time.

42 (Pages 162 to 165)

Page 166 Page 168 1 QUESTIONS BY MS. BRANSCOME: 1 you with specific percentages, and so I'm 2 O. Okay. You talk about, in 2 asking you, is that something that as a paragraph 35 primarily -- we'll talk about 3 3 toxicologist would be important information the fragrance components in more detail, but 4 4 to you? you talk about the idea of chemicals being a 5 5 Depends. Certainly with the potential irritant. 6 fragrance -- and I'm talking about the 6 7 conversation about this paragraph is focusing 7 Are you familiar with that? 8 A. Yes, that's correct. 8 on the fragrance components. 9 Q. Is it your position that any 9 So, yes, I mention that it product that contains chemicals that could be 10 would be nice to know, it would be good to 10 an irritant should be labeled with a health know, if we could, exactly what was in there, 11 11 12 because I could quantify the hazard or 12 warning? 13 MS. PARFITT: Objection. 13 quantify the risk, actually. So instead, I MR. MEADOWS: Okay. have -- I identify it as a hazard, but I 14 14 15 THE WITNESS: I don't think 15 can't quantify it without those levels. 16 that's -- no, I don't think I've 16 But does that change -- make a 17 formed that specific opinion. 17 difference in the overall conclusions I draw? But the opinion that I think No, it doesn't affect the overall conclusions 18 18 19 I'm expressing here is that when you 19 that I have drawn, but it adds that other 20 have a -- the information that I have, 20 piece of the puzzle that deals with the fact 21 which unfortunately the company hasn't 21 that we have a complex mixture that have a 2.2 given us percentages or actual levels, 2.2 combination of ingredients that target 23 instead, what I do as a toxicologist, 23 irritation. 24 I look at what is there. And when I 24 And irritation and the 25 25 see over a hundred chemicals there, potential to produce an inflammatory Page 167 Page 169 1 that 70 percent of them have been 1 response, in my -- if you've read my report, 2 linked as an irritant hazard, there is 2 you understand that I think that's a key 3 the issue of toxicological additivity 3 factor in increasing the risk for ovarian 4 4 to consider. cancer. 5 So certainly as a risk 5 Understanding the percentages assessor, when I have that many 6 of the constituent components, is that 6 7 7 limited only to fragrance, or would it also potential sources of irritation as far 8 as chemicals going into a complex 8 be important to understand the percentages 9 mixture, certainly I think I have 9 for the heavy metals that you contend are in 10 formed the opinion that I think that 10 Johnson's baby powder? 11 is something that needs to be 11 A. So if I was trying to define considered when you're talking about 12 the hazard of each component, I would 12 13 providing information to consumers, 13 certainly want one to know that. As a result, what I'm doing instead is looking at 14 yes. 14 the complex mixture. In other words, this is QUESTIONS BY MS. BRANSCOME: 15 15 16 Q. As a toxicologist, would it be 16 a mixture of all these things. 17 important to you to understand the exact 17 I break out those individual 18 percentages of all of the constituent 18 components, or constituents, to tell you 19 components of, say, Johnson's baby powder, 19 about the hazard that is brought to play or 20 20 the toxicity profiles that exists. And for example? 21 A. Are you talking about just the 21 what's important about that in my overall fragrance or are you talking about everything 22 22 evaluation of the end product, which is what my risk assessment is based on, the end 23 that's in it? 23 24 Q. Dr. Plunkett, you referenced 24 product, shows that I have multiple 25 the fact that the company has not provided 25 components with similar types of effects.

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Page 170

And as a toxicologist, when you do that, that affects the conclusion that you can draw about a body of literature.

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Q. Okay. You do understand that there is testing data available about the percentages of the constituent components with respect to heavy metals, et cetera, that have been in Johnson's baby powder over time, correct?

A. There is some information. Unfortunately, the information is not complete as to every lot or every sample, as far as what I have seen. And also, there's some -- some of the sampling is reported as more of a limit versus an actual quantification. So it depends upon which -which result, study result or document, you're looking at.

There is some there, yes, and that's one of the reasons why I identified these as part of my risk assessment, because I look for a pattern of these metals that are known to carry a hazard and whether or not these are ones I'm seeing detected time and time again.

using a word such as an increase -- an increased risk.

Is that a specific number? Am I telling you that it's increased by two times or four times or six times? No. The data available did not allow us to do that, with the exception of the epidemiological data. And the epidemiological data can show you that in that piece of evidence there appears to be a 30 percent increased risk above background.

Q. Did you make an attempt to quantify the risk with the data that you had available to you with respect to the final consumer product?

A. I could not, based on the data I had, because I didn't have a well-controlled animal study to be able to pull that out that way.

Instead, what I -- in this type of weight of the evidence, you look at what you might be able to quantify based on the human data. And certainly the human data showing the statistically significant consistent findings across studies for that

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Q. But you made no attempt to quantify the risk with respect to any of those components or use that data in any way, correct?

MS. PARFITT: Objection. Form. THE WITNESS: No, I used that -- that data as part of -- my risk assessment as part of my hazard assessment, absolutely. It's part of the hazard assessment.

But as far as quantifying them individually, no. I am quantifying the risk and looking at the risk of the entire product, not of just one individual component of the product. **OUESTIONS BY MS. BRANSCOME:**

Q. Well, we already discussed you're not quantifying the risk with respect to the entire product, correct?

A. Well, I'm quantifying it in terms of an increase above background, which I'm not giving you a -- I told you I wasn't giving you a cancer potency factor. That is true. That I am not doing.

But I am quantifying it by

Page 173

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30 percent increased risk, that is part of my overall weight of the evidence for me making the statement the risk is increased.

But you'll notice I don't say increased risk of 30 percent, because I don't believe that I can state that with certainty in the way I do a risk assessment. But certainly as any one individual -- any one individual piece of evidence or any one body, like the epi data, others have made -- other bodies who have looked at the -- talked about the consistency of the increased risk signal in the epi studies as being in the range of 30 percent.

Q. Okay. But you would agree that based on the methodology that you applied in this case, you could not say to a reasonable degree of scientific certainty that there is an increased risk of, for example, 30 percent with respect to use of Johnson's baby powder and ovarian cancer, correct?

MR. MEADOWS: Objection. THE WITNESS: I have not done that. And I'm not saying that somebody else couldn't do that. I

44 (Pages 170 to 173)

Page 174 Page 176 1 1 have not -- I have not chosen to do Q. Is it your opinion as you sit 2 2 that based on my evaluation of the here today that someone could develop ovarian 3 3 cancer through -- exclusively through the data. 4 inhalation of Johnson's baby powder? 4 QUESTIONS BY MS. BRANSCOME: 5 MS. PARFITT: Objection. 5 O. And the same would be true if I 6 6 THE WITNESS: I haven't formed asked that question and substituted any 7 7 that opinion at this point in time. particular number, a 10 percent increased 8 **QUESTIONS BY MS. BRANSCOME:** 8 risk, a 20 percent increased risk, correct? 9 9 MR. MEADOWS: Objection. Q. Have you done any analysis or 10 10 can you point me to any analysis in your THE WITNESS: I haven't given a specific number in my final opinions, 11 report that makes a comparison of the 11 12 exposure levels that might be seen in an 12 that is true. 13 13 occupational setting to what would be seen by **OUESTIONS BY MS. BRANSCOME:** 14 a consumer? 14 Okay. 15 15 A. Are you asking me for a piece A. I've tried to explain to you 16 what evidence I do think is there, however. 16 of evidence that does that comparison, or is 17 there evidence that allows you to do that 17 Q. Now, we've talked about 18 comparison? 18 different types of talc that might have 19 Q. Have you cited or discussed any 19 different constituent components, but you 20 20 also look at exposure to talc in an of the evidence or done an analysis in any 21 21 occupational setting. way that would compare exposure levels in an 22 Do you recall that? 22 occupational setting to what you would 23 23 anticipate a consumer using Johnson's baby Some of the studies that I've 24 powder might be exposed to? 24 relied upon, yes, some of them were 25 A. I don't think I did it as a 25 occupational. Page 175 Page 177 1 separate analysis, but as part of my analysis 1 Q. Okay. And you understand that 2 2 in an occupational setting, you would agree I considered evidence that showed -- provided 3 3 that the exposure, particularly via me with such data. So, for example, if you 4 inhalation, would be much higher than it 4 want, I can point you to a -- I have an 5 would be through the use of a consumer 5 inhalation paragraph, I think. 6 6 product, correct? Let me look for it real quick. 7 7 See if I can find it quickly for you. I A. It depends on the occupation, 8 8 but, yes. For example, I would agree a miner don't want to waste your time. 9 9 would be expected to have that, but there are O. Sure. 10 certain, quote/unquote, occupational studies 10 A. So there's -- I don't see it 11 where the exposure levels that -- for 11 cited here, but there's at least one document 12 example, there are -- I believe there's at 12 I reviewed where the company themselves made 13 least one study that looked at application of 13 a comparison, and I have seen that, of 14 talc powders in -- maybe in a material, 14 inhalation exposure to talc suspended in air 15 coating materials in a factory. Those kinds 15 with diapering. Dr. Longo has done a 16 of studies would be different than a mining 16 measurement of exposure in air with perineal 17 study. 17 application of talc. So I'm aware of those 18 But, certainly, yes, I 18 studies. 19 understand that occupational studies, the 19 And then I certainly am aware 20 inhalation exposure is the pathway that would 20 of the fact that those numbers are different, 21 be predominant versus in the consumer body 21 or smaller, than many of the numbers I see 22 22 powder use, I'm talking about the predominant reported in some of the occupational studies. 23 exposure pathway in my opinion is going to be 23 But I can't say that's true for all. 24 through perineal use, even though inhalation 24 I would certainly, though, say 25 exposure can occur. 25 that if you're just talking inhalation, I

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        certainly would expect a miner or a miller to
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                                                                  QUESTIONS BY MS. BRANSCOME:
 2
        have a greater potential for inhalation
                                                            2
                                                                      Q. Okay. Now, you would agree
 3
        exposure than routine use of the consumer
                                                            3
                                                                  that -- so let's set aside inhalation.
 4
        product, with the exception of the studies --
                                                            4
                                                                          You agree that for talc -- for
 5
        the reports of large amounts of exposure in
                                                            5
                                                                  Johnson's baby powder or another one of
 6
        children where the inhalation -- where they
                                                            6
                                                                  Johnson & Johnson's consumer talc products to
 7
        were inhaling large amounts of powder.
                                                            7
                                                                  reach an individual's ovaries, it must pass
 8
              And so that's a different
                                                            8
                                                                  from the perineum, through the vagina and the
 9
        story. That's sort of an acute overdose
                                                            9
                                                                  cervical canal, move across the uterus -- and
10
        exposure, I guess, versus the typical daily
                                                          10
                                                                  again, it's the ciliary motion of the
        exposure through occupational or consumer
11
                                                                  fallopian tubes -- cross the peritoneal space
                                                          11
12
                                                          12
                                                                  between the fimbriae and ovaries, escape
        use.
13
           O. And that raises an interesting
                                                                  phagocytosis in the peritoneal space, and
                                                          13
                                                                  then attach to the surface of the ovaries,
14
        question. You discuss health hazards
                                                          14
15
        associated with talc being known, and in some
                                                          15
                                                                  correct?
16
        cases deaths had been reported.
                                                          16
                                                                          MS. PARFITT: Objection. Form.
17
          You're aware that those relate
                                                                          MR. MEADOWS: Okay.
                                                          17
18
       to asphyxiation deaths, correct?
                                                          18
                                                                          THE WITNESS: If the issue is
           A. Or long-term injury to lungs.
19
                                                                      attaching to the surface, yes.
                                                          19
20
        Maybe not an immediate asphyxiation, but lung
                                                          20
                                                                      There's also some information
21
        damage produced by large amounts -- some of
                                                          21
                                                                      indicates the site of attack may be
22
        the children would go to the hospital and be
                                                          22
                                                                      actually at the fallopian tube exit to
23
        sick for a while and then die. So they
                                                          23
                                                                      the peritoneum. But, yes, that's
24
        didn't asphyxiate immediately, right? But
                                                          24
                                                                      correct, there's been some discussion
        some of them did. You're exactly right.
                                                          25
25
                                                                      in the literature on ovarian cancer
                                         Page 179
                                                                                                   Page 181
                                                                      about whether the tumors are arising
 1
                Both of those things occur, and
                                                            1
 2
        I address that also in my warning section
                                                            2
                                                                      in the tubes versus the ovaries.
 3
        about the fact that that warning didn't --
                                                            3
                                                                          But I would agree, I think
 4
        was not put on the product for a long period
                                                            4
                                                                      both -- I think both of those
 5
        of time even though those types of reports
                                                            5
                                                                      things -- those things -- there is a
 6
        were coming in early.
                                                            6
                                                                      passage that has to happen, regardless
 7
          O. You would agree that that is a
                                                            7
                                                                      of whether the end point is at the
 8
        completely different biologic mechanism than
                                                            8
                                                                      fallopian tube or at the ovary.
 9
                                                                   QUESTIONS BY MS. BRANSCOME:
                                                            9
        what you are proposing the biological
10
        mechanism is for ovarian cancer to develop
                                                          10
                                                                      Q. Okay. Is it your view that the
11
        with respect to talc use, correct?
                                                          11
                                                                   consensus has been reached that ovarian
12
                MR. MEADOWS: Objection.
                                                          12
                                                                  cancer can be caused by talc landing in the
13
                THE WITNESS: I would agree
                                                          13
                                                                   fallopian tubes?
14
           that it's an acute response versus
                                                          14
                                                                      A. I haven't formed that opinion,
15
           chronic, yes, that I agree with.
                                                          15
                                                                   though I do believe this will be discussed by
16
               It's not entirely different in
                                                                  some of the other experts.
                                                          16
                                                                      Q. Okay. Have you personally
17
           some cases because some of the tissue
                                                          17
                                                                   conducted any tests or experiments to confirm
18
           reactions you saw were indicative of
                                                          18
19
           irritation when some of the lung
                                                          19
                                                                  the theory that talc migrates from
20
           samples were looked at. But
                                                          20
                                                                  application at the perineum to the ovaries?
21
           certainly, yes, that's acute exposure
                                                          21
                                                                      A. If by that you mean something
22
                                                                   where I performed a laboratory test myself,
           versus chronic exposure, and I'm
                                                          22
23
           focusing on ovarian cancer on chronic
                                                          23
                                                                  no. I have not done that.
24
            exposure scenarios.
                                                          24
                                                                      Q. As a toxicologist, are you
25
                                                           25
                                                                  capable of doing that?
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46 (Pages 178 to 181)

Page 182 Page 184 1 1 Yes, I believe if asked I And then on top of that, you 2 2 could -- I could attempt to design something have the review articles that talk about 3 to look at that issue. 3 migration of particles in the female 4 reproductive tract and are describing it as Q. Okay. 4 5 But I would argue that I think an event that is known to occur. So it's 5 A. 6 6 it doesn't make a lot of sense to revisit those things weighed together. 7 7 based upon what we already know from the But certainly routine could be 8 supported by the observations where the 8 scientific literature and the review papers 9 from the gynecological community. I believe 9 majority of the patients in the studies were 10 it's -- it's understood that it can migrate. 10 showing movement of inert particles. Q. In your opinion, has an animal Q. Is it your opinion that every 11 11 model been successfully developed that would 12 perineal application of cosmetic talc powder 12 13 allow the testing of talc migration in humans 13 results in talc being deposited on the from the perineum to the ovaries? 14 14 ovaries? 15 A. I think I tell that you in my 15 I have not formed that opinion, A. 16 report. I believe that the human data is the 16 no. 17 relevant data to look at this issue. 17 Q. Have you formed an opinion as 18 So it would be very difficult 18 to with what frequency -- so let's say to design a study to do this based on the someone uses a cosmetic talc on a perineal 19 19 application ten times. Out of those ten 20 typical laboratory species that are used in 20 21 toxicology testing. Even -- even the monkeys 21 times, have you formed an opinion as to how 22 have issues, and the biggest issues with 22 many of those instances would talc deposit on 23 monkeys is the ethicality of using a monkey 23 the ovaries? to settle -- to address a question that I 24 24 MS. PARFITT: Objection. 25 25 believe is settled within the gynecological THE WITNESS: I haven't formed Page 183 Page 185 an opinion in that particular way, no. 1 and scientific community. 1 2 2 Q. Now, you state in your report I think what I've -- I've tried to 3 that talc that's applied through perineal 3 describe to you in my report is that I 4 use -- I believe the term you use --4 believe it is known that inert 5 5 routinely migrates to the ovaries. particles have the ability to migrate. 6 Is that your opinion? 6 And based on that, I form the opinion 7 7 that it's my opinion to a reasonable A. Are you reading from my report? degree of scientific certainty, which 8 MR. MEADOWS: To the extent 8 9 9 that question is still lingering, I would be a more likely than not 10 object to it. 10 standard, that particles of talc would 11 **QUESTIONS BY MS. BRANSCOME:** 11 be migrating when women are using them 12 12 perineally. But I haven't told you On paragraph 43 on page 29. 13 So I think as I've stated it, 13 that it has to be a specific number, 14 the studies that I have reviewed demonstrate 14 no. 15 15 that inert particles routinely move from the **OUESTIONS BY MS. BRANSCOME:** 16 16 lower female reproductive tract up into Q. Have you done any analysis to 17 fallopian tubes and towards the ovaries. 17 establish over a lifetime use of cosmetic 18 What do you mean by routinely? 18 talc where the app -- the perineal Q. 19 A. It's the percentages of 19 application, with what frequency during a 20 lifetime the talc may have been deposited on movement that are reported in the patients. 20 21 21 that individual's ovaries? In other words, if you look at some of the 22 22 So I certainly looked for individual studies -- if you want we can pull 23 them out, but, you know, eight of ten 23 information to allow me to assess that, but patients, nine of ten patients, all the 24 24 unfortunately those kinds of studies would be 25 patients showed movement of the particles. 25 unethical to do. Because that would be a

47 (Pages 182 to 185)

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	Page 186		Page 188
1	matter of sampling women during using them	1	MS. BRANSCOME: Okay. Can we
2	and then taking biopsies, and that's	2	just go off the record for a second?
3	something that would be difficult to do. I	3	VIDEOGRAPHER: We are going off
4	would say impossible to get approval to do	4	the record at 12:23 p.m.
5	under human testing guidelines.	5	(Off the record at 12:23 p.m.)
6	Q. Okay. So it's your opinion	6	VIDEOGRAPHER: We are back on
7	that it is possible for tale that is applied	7	the record at 12:24 p.m.
8	through a perineal application to reach the	8	QUESTIONS BY MS. BRANSCOME:
9	ovaries, but you cannot say with what	9	Q. As you sit here today, how
10	frequency that occurs?	10	would you characterize the biological
11	MS. PARFITT: Objection. Form.	11	mechanism by which you claim Johnson's baby
12	Misstates her testimony.	12	powder, their other cosmetic talc products,
13	THE WITNESS: That's not	13	present a risk of ovarian cancer?
14	what I'm telling you is, I think it	14	A. So I outline this for you in
15	that to a reasonable degree of	15	the MDL report. I think I have a section
16	scientific certainty that it migrates,	16	on let's see if I can you want me to
17	and that would be the standard of more	17	tell you where or
18	likely than not. I think it's more	18	So paragraph 65, I think I set
19	likely than not that the talc is	19	out part of this argument or part of this.
20	reaching the ovaries when people are	20	And then also in paragraph I believe in
21	using it perineally.	21	67.
22	I did form the opinion and	22	Q. All right. Well, let me take a
23	I've talked about this at trial and	23	step back.
24	yesterday. I have formed the opinion	24	Is it your opinion that the
25	that this is a issue of chronic or	25	biological mechanism by which tale, cosmetic
25	that this is a issue of chronic of	23	biological incentainshi by which tale, cosmetic
	Page 187		Page 189
1	or use of the products. In other	1	talc, can in your view cause ovarian cancer,
2	words, people aren't just using it	2	is that something that has been definitively
3	once, but people are using it you	3	established?
4	can use the word "routinely," as a	4	A. What do you mean by
5	habit, in their daily life perineally.	5	definitively? I mean, I think I believe
6	And that would be consistent with the	6	more likely than not that so I believe I
7	studies that have been done that have	7	have reached a conclusion that I think what
8	looked at the issue of dose response.	8	the most likely biologically plausible
		1	
9	And I discuss that in my	9	
9 10	And I discuss that in my report, too.	9	mechanism, but maybe you're ask meaning something else.
	report, too.	1	mechanism, but maybe you're ask meaning something else.
10	report, too. QUESTIONS BY MS. BRANSCOME:	10	mechanism, but maybe you're ask meaning
10 11	report, too. QUESTIONS BY MS. BRANSCOME: Q. Okay. But you have not made an	10 11	mechanism, but maybe you're ask meaning something else. Q. Okay. Well, let's start with specifically you discuss a number of
10 11 12 13	report, too. QUESTIONS BY MS. BRANSCOME: Q. Okay. But you have not made an attempt to quantify, nor have you seen it in	10 11 12	mechanism, but maybe you're ask meaning something else. Q. Okay. Well, let's start with specifically you discuss a number of different potential mechanisms in your
10 11 12	report, too. QUESTIONS BY MS. BRANSCOME: Q. Okay. But you have not made an attempt to quantify, nor have you seen it in the literature, the overall dose of talc that	10 11 12 13	mechanism, but maybe you're ask meaning something else. Q. Okay. Well, let's start with specifically you discuss a number of different potential mechanisms in your report. So if you believe you have reached
10 11 12 13 14 15	report, too. QUESTIONS BY MS. BRANSCOME: Q. Okay. But you have not made an attempt to quantify, nor have you seen it in the literature, the overall dose of talc that someone might be exposed to in terms of	10 11 12 13 14	mechanism, but maybe you're ask meaning something else. Q. Okay. Well, let's start with specifically you discuss a number of different potential mechanisms in your report. So if you believe you have reached an opinion more likely than not about the
10 11 12 13 14 15	report, too. QUESTIONS BY MS. BRANSCOME: Q. Okay. But you have not made an attempt to quantify, nor have you seen it in the literature, the overall dose of talc that someone might be exposed to in terms of contact with the ovaries throughout their	10 11 12 13 14 15 16	mechanism, but maybe you're ask meaning something else. Q. Okay. Well, let's start with specifically you discuss a number of different potential mechanisms in your report. So if you believe you have reached an opinion more likely than not about the specific biological mechanism by which
10 11 12 13 14 15 16 17	report, too. QUESTIONS BY MS. BRANSCOME: Q. Okay. But you have not made an attempt to quantify, nor have you seen it in the literature, the overall dose of talc that someone might be exposed to in terms of contact with the ovaries throughout their lifetime, chronic use of cosmetic talc?	10 11 12 13 14 15 16 17	mechanism, but maybe you're ask meaning something else. Q. Okay. Well, let's start with specifically you discuss a number of different potential mechanisms in your report. So if you believe you have reached an opinion more likely than not about the specific biological mechanism by which cosmetic talc and specifically Johnson &
10 11 12 13 14 15 16 17	report, too. QUESTIONS BY MS. BRANSCOME: Q. Okay. But you have not made an attempt to quantify, nor have you seen it in the literature, the overall dose of talc that someone might be exposed to in terms of contact with the ovaries throughout their lifetime, chronic use of cosmetic talc? MS. PARFITT: Objection. Form.	10 11 12 13 14 15 16 17 18	mechanism, but maybe you're ask meaning something else. Q. Okay. Well, let's start with specifically you discuss a number of different potential mechanisms in your report. So if you believe you have reached an opinion more likely than not about the specific biological mechanism by which cosmetic talc and specifically Johnson & Johnson's products can cause ovarian cancer,
10 11 12 13 14 15 16 17 18	report, too. QUESTIONS BY MS. BRANSCOME: Q. Okay. But you have not made an attempt to quantify, nor have you seen it in the literature, the overall dose of talc that someone might be exposed to in terms of contact with the ovaries throughout their lifetime, chronic use of cosmetic talc? MS. PARFITT: Objection. Form. THE WITNESS: Those that's	10 11 12 13 14 15 16 17 18	mechanism, but maybe you're ask meaning something else. Q. Okay. Well, let's start with specifically you discuss a number of different potential mechanisms in your report. So if you believe you have reached an opinion more likely than not about the specific biological mechanism by which cosmetic talc and specifically Johnson & Johnson's products can cause ovarian cancer, can you describe that for me?
10 11 12 13 14 15 16 17 18 19 20	report, too. QUESTIONS BY MS. BRANSCOME: Q. Okay. But you have not made an attempt to quantify, nor have you seen it in the literature, the overall dose of talc that someone might be exposed to in terms of contact with the ovaries throughout their lifetime, chronic use of cosmetic talc? MS. PARFITT: Objection. Form. THE WITNESS: Those that's the kinds of studies that have not	10 11 12 13 14 15 16 17 18 19 20	mechanism, but maybe you're ask meaning something else. Q. Okay. Well, let's start with specifically you discuss a number of different potential mechanisms in your report. So if you believe you have reached an opinion more likely than not about the specific biological mechanism by which cosmetic talc and specifically Johnson & Johnson's products can cause ovarian cancer, can you describe that for me? A. So it's a chronic inflammatory
10 11 12 13 14 15 16 17 18 19 20 21	report, too. QUESTIONS BY MS. BRANSCOME: Q. Okay. But you have not made an attempt to quantify, nor have you seen it in the literature, the overall dose of talc that someone might be exposed to in terms of contact with the ovaries throughout their lifetime, chronic use of cosmetic talc? MS. PARFITT: Objection. Form. THE WITNESS: Those that's the kinds of studies that have not been done and I believe could not be	10 11 12 13 14 15 16 17 18 19 20 21	mechanism, but maybe you're ask meaning something else. Q. Okay. Well, let's start with specifically you discuss a number of different potential mechanisms in your report. So if you believe you have reached an opinion more likely than not about the specific biological mechanism by which cosmetic talc and specifically Johnson & Johnson's products can cause ovarian cancer, can you describe that for me? A. So it's a chronic inflammatory process, and so but like all compounds,
10 11 12 13 14 15 16 17 18 19 20 21 22	report, too. QUESTIONS BY MS. BRANSCOME: Q. Okay. But you have not made an attempt to quantify, nor have you seen it in the literature, the overall dose of talc that someone might be exposed to in terms of contact with the ovaries throughout their lifetime, chronic use of cosmetic talc? MS. PARFITT: Objection. Form. THE WITNESS: Those that's the kinds of studies that have not been done and I believe could not be done based upon ethics of human	10 11 12 13 14 15 16 17 18 19 20 21	mechanism, but maybe you're ask meaning something else. Q. Okay. Well, let's start with specifically you discuss a number of different potential mechanisms in your report. So if you believe you have reached an opinion more likely than not about the specific biological mechanism by which cosmetic talc and specifically Johnson & Johnson's products can cause ovarian cancer, can you describe that for me? A. So it's a chronic inflammatory process, and so but like all compounds, constituents, even drugs that we look at, we
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10 11 12 13 14 15 16 17 18 19 20 21 22	report, too. QUESTIONS BY MS. BRANSCOME: Q. Okay. But you have not made an attempt to quantify, nor have you seen it in the literature, the overall dose of talc that someone might be exposed to in terms of contact with the ovaries throughout their lifetime, chronic use of cosmetic talc? MS. PARFITT: Objection. Form. THE WITNESS: Those that's the kinds of studies that have not been done and I believe could not be done based upon ethics of human	10 11 12 13 14 15 16 17 18 19 20 21	mechanism, but maybe you're ask meaning something else. Q. Okay. Well, let's start with specifically you discuss a number of different potential mechanisms in your report. So if you believe you have reached an opinion more likely than not about the specific biological mechanism by which cosmetic talc and specifically Johnson & Johnson's products can cause ovarian cancer, can you describe that for me? A. So it's a chronic inflammatory process, and so but like all compounds, constituents, even drugs that we look at, we

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there are certain components to the process	discuss those issues.
there are certain components to the process of cancer that are consistent with the effects produced by talc, and we know that talc can produce a chronic inflammatory process. And so that's why I was pointing you to the paragraph 65 and I think 67.	discuss those issues. I think it's consistent with I don't know if the ACOG statement goes that far on mechanism, but it does talk about ovarian cancer. That's a recent statement. And I believe it's consistent with some of the I believe my opinions are consistent with some of the opinions reached by others in science, but that's the only way
effects produced by talc, and we know that	I don't know if the ACOG statement goes that
tale can produce a chronic inflammatory	far on mechanism, but it does talk about
process.	ovarian cancer. That's a recent statement.
And so that's why I was	And I believe it's consistent
pointing you to the paragraph 65 and I think	7 with some of the I believe my opinions are
67.	8 consistent with some of the opinions reached
Q. Is it your opinion that	by others in science, but that's the only way
consensus has been reached in the scientific	I can answer that for you.
community that cosmetic talc can cause	Q. Okay. Because you have not,
ovarian cancer through a chronic inflammatory	one way or the other, done an evaluation of
response?	whether or not chronic inflammatory process
MS. PARFITT: Objection.	is a biological mechanism on which the
THE WITNESS: I don't know that	scientific community has reached general
that's exactly the opinion I've	consensus with respect to the causation of
formed.	ovarian cancer; is that correct?
Would you like me to I could	MR. MEADOWS: Objection.
restate what I believe, but I don't	THE WITNESS: I can't tell you
think that's exactly how I would state	that I can't tell you that every
it, no.	body that's looked at it, but I have
QUESTIONS BY MS. BRANSCOME:	tried to point you to evidence that I
Q. Okay. So then yes or no: Has	believe is consistent with that.
consensus been reached in the scientific	For example, the IARC would be
community that cosmetic talc can cause	a good example of consensus on
Page 191	Page 193
ovarian cancer through a chronic inflammatory	biologic mechanism because they have a
	oronogre meenamem occause mey mave a
process?	whole part of their assessment of
A. I don't believe I formed the	whole part of their assessment of non-asbestiform tale and perineal
A. I don't believe I formed the opinion either way, that it's yes or no,	whole part of their assessment of non-asbestiform talc and perineal cancer of perineal use and ovarian
process? A. I don't believe I formed the opinion either way, that it's yes or no, because I haven't tried to I haven't tried	whole part of their assessment of non-asbestiform talc and perineal cancer of perineal use and ovarian cancer that discusses mechanism. And
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Page 194 Page 196 1 Q. Okay. When we talk about the 1 are known to be able to produce, 2 idea of biologic -- a biologically plausible 2 specifically, ovarian cancer. 3 mechanism, what is your understanding of the 3 QUESTIONS BY MS. BRANSCOME: term "plausible" in that expression? 4 4 Q. Is it your opinion that IARC, 5 5 A. When I use the word for example, has concluded that the б 6 "biologically plausible mechanism" or biological mechanism by which talc may cause 7 "biologic plausibility," I'm using it 7 ovarian cancer is chronic inflammation? 8 consistent with what Bradford Hill uses, 8 MS. PARFITT: Objection. 9 that's it's the idea that the evidence that 9 THE WITNESS: I don't know that 10 available makes -- the evidence that 10 they have used -- they've described it 11 11 quite that way, but they do describe available supports a pathway where you can go what they believe is the biologically 12 to exposure to response. 12 13 So in other words, there's a --13 plausible mechanism. Because they do organize and use within the 14 the biological information is consistent with 14 15 how we know cancer can develop. That's the 15 definitions of how they describe some 16 response we're looking at. And the exposure 16 things that are consistent with what 17 we're looking at is known to produce those 17 Bradford Hill uses. kind of biologic events. 18 QUESTIONS BY MS. BRANSCOME: 18 Q. Okay. And obviously you're 19 So as a result, based upon 19 20 knowing that there's a consistency between 20 familiar with the IARC evaluation of talc 21 the data that we have on the -- on the 21 with respect to the possibility of causing 22 exposure and the data that we have on the way 22 ovarian cancer, correct? cancer can occur, those things -- those 23 23 Yeah. If you mean the recent one, yes, the most recent assessment. 24 things align. So that makes it biologically 24 Q. Yes. 25 plausible that that could occur. 25 Page 195 Page 197 1 Q. But you would agree that 1 And that IARC has in fact biological plausibility suggests that it is a 2 2 classified cosmetic talc not containing 3 plausible explanation, but it may not have 3 asbestos as possibly carcinogenic to humans, 4 been established as the definitive pathway by 4 correct? 5 which a disease is caused, correct? 5 A. It's a possible human carcinogen 2B, that's correct. MS. PARFITT: Objection. Form. 6 6 7 7 Q. Okay. And if a product is THE WITNESS: Well, I would 8 8 agree that in the discussion of listed in the 2B category, does that 9 biologic plausibility in the Bradford 9 necessarily mean the product, in your view, 10 Hill paper that is true. But if you 10 is carcinogenic? 11 look at people's discussion of the use 11 A. Not always, because that comes of -- I want to say "biological 12 down to an assessment of -- then you're 12 13 mechanism" rather than the word 13 putting together a -- a risk assessment that "biologic plausibility," because 14 looks at -- looks at -- across the 14 15 really as a toxicologist I'm trying to 15 information that you have available. And understand whether there's a biologic 16 16 that may be that -- that the -- the possible 17 mechanism that makes sense. Those are 17 is all you can say, or it may be that you 18 words I like to use. Does it make 18 believe that the information -- there's 19 19 enough information there to take it further. sense that this exposure could lead to 20 20 Has a possibility -- that's this response. 21 And that involved looking at 21 what I said, they do a hazard assessment. 22 22 They rank things on hazard based on -- on the mechanistic data or the data on the way toxic responses are produced unlikely -- not enough evidence, less -- the 23 23 24 by talc, and whether or not they align 24 possibility, the probability or it's known. 25 with the types of toxic insults that 25 Q. In your opinion, is your

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Page 198 Page 200 1 characterization of the risk of Johnson's 1 opinion. 2 baby powder or talcum powder products with 2 Q. Is there a threshold of the use 3 respect to ovarian cancer, are you in the MDL 3 of Johnson & Johnson's talcum powder products characterizing that risk as a higher level of 4 below which there is no increased risk, in 4 5 risk than what IARC characterized it, or do your opinion, of ovarian cancer? 5 6 6 you agree with the 2B characterization of A. We have not identified that 7 possibly carcinogenic? 7 threshold. That's what's missing within 8 MS. PARFITT: Objection. Form. 8 the -- the literature that exists today. So 9 THE WITNESS: So I'm not IARC, 9 I can't tell you whether or not with only a 10 so I don't try to second-guess there. 10 thousand applications over a lifetime that 11 They have reached a conclusion, and I 11 is -- is not enough for every individual or 12 use that as part of my weight of the 12 not, but certainly I do believe that the --13 evidence. So I haven't formed the that the exposure has to be habit, routine, 13 14 opinion they're right or wrong. 14 chronic, something that is done maybe not on 15 But I have done a different 15 a daily basis but on a routine basis in a 16 assessment. My assessment, first off, 16 woman's life. 17 includes more information than IARC 17 So that is consistent, I think, 18 had, so as a result, I have formed the 18 with the literature. 19 MS. BRANSCOME: Okay. We can conclusion that I believe that it's 19 20 more likely than not that exposure 20 go off the record. 21 21 to -- perineal exposure to talc body VIDEOGRAPHER: We are going off 22 powders increases the risk of ovarian 22 the record at 12:36 p.m. 23 cancer in women who use that product. 23 (Off the record at 12:36 p.m.) 24 And I will put the caveat this VIDEOGRAPHER: We are back on 24 25 has to be chronic use or repeated use, 25 the record at 1:35 p.m. Page 199 Page 201 1 1 because I've gone -- I've said that QUESTIONS BY MS. BRANSCOME: 2345678 many times. 2 Q. Good afternoon again, So that -- that is my opinion. 3 Dr. Plunkett. So that's a different statement and a 4 A. Good afternoon. 5 different assessment than what IARC I want to talk a little bit 6 about the Health Canada assessment. does. 7 But -- so I don't disagree with We talked about this before, but this is something that you reviewed after their possible -- I weigh that, but I 8 9 believe the evidence for the risk 9 you completed your report which has been 10 assessment shows me that it's more 10 marked as Exhibit 4, correct? 11 likely than not that this -- this 11 A. Yes, and I wanted to tell you, 12 exposure will increase the risk above 12 I did not bring all those documents printed. 13 a background risk for women who are 13 I apologize. So there is a separate Health 14 using this product. 14 Canada draft risk assessment that I didn't 15 **OUESTIONS BY MS. BRANSCOME:** 15 print. 16 Q. And how do you define chronic 16 Q. Okay. So when you're referring 17 or repeated use? 17 to the Health Canada analysis, what document 18 Well, that is variable within are you specifically referring to? A. 18 19 the literature. For me, chronic is 19 A. So I'm referring to the -- the 20 exposure -- if as a toxicologist, I would 20 combined documents, but there are times when 21 typically say chronic use is years of use. 21 you've asked me questions that I've been It doesn't have to be daily, but it would be 22 22 referring -- and I tried to say, I believe, years. That's the most common description 2.3 23 Taher. 24 you see in toxicology, so I would say that's 24 But, yes, some of the questions 25 fair. That's a fair assessment of my 25 you asked me when I said Health Canada, I was

Page 202 Page 204 1 talking about the combined documents, which 1 there is a association between those two 2 would include their -- I guess it's called a 2 things, the exposure and the response, which 3 draft risk assessment document, yeah, which 3 is more than a possible association, if you 4 want to use those words. 4 refers to this document but is a separate --5 5 is their own separate statement. But my assessment that I've 6 6 As you sit here today, what is done is not exactly the same, for example, as 7 your understanding of the current position 7 IARC does, which is more of just a hazard 8 that has been articulated in the collection 8 assessment. 9 of documents that you refer to as Health 9 Q. Right. 10 Canada with respect to any potential 10 So I'm focusing my questions relationship between cosmetic talc and now on your risk assessment as compared to 11 11 the documents that you've supplied us with 12 ovarian cancer? 12 with respect to Health Canada. And if I 13 A. So that's why I did print out 13 14 the small one, because I think it summarized understand it correctly, are you stating that 14 15 it. So here, if you look at this Exhibit 6, 15 your opinion with respect to the relationship 16 it makes specific conclusions or draws --16 between cosmetic talc and ovarian cancer, you makes statements. And essentially it talks 17 believe that it is an association that is 17 18 about talc being a possible risk of ovarian 18 stronger than a possible risk; is that cancer, but then it gives women specific 19 19 correct? advice about what to do in order to minimize 20 A. Well, I don't say it's a 20 21 possible risk; I say there is an increased 21 exposure to the products, and some of that 22 was relevant as well. 22 risk. So I think it's a different statement, 23 Just one reason I printed it 23 yes, absolutely. 24 Of course, I'm not Health 24 out, it has to do with either choosing an 25 25 alternative product or avoiding genital Canada, so, you know, they have a framework Page 203 Page 205 upon which they make decisions, and I'm doing 1 exposure to talc. 2 an analysis based on what I have done. And 2 And let me see the exact words 3 3 that they use, but -so it's not exactly the same, although some 4 Q. Before you do that, do you 4 of the same documents and information is 5 5 agree with the characterization that cosmetic weighed within -- and then that's when you 6 talc presents a possible risk of ovarian have the issue of what Health Canada does 6 7 7 versus what they rely upon. cancer? 8 8 But this Taher risk assessment A. No, I don't think that's my 9 9 opinion. I think my opinion is stronger than is just one piece of information that Health 10 that. 10 Canada has weighed in their assessment if you 11 But are you talking about my 11 read their -- their draft risk assessment. 12 causation analysis opinion or just my risk 12 Q. So the question I have about 13 assessment opinion? 13 the Taher risk assessment, earlier you were 14 Q. I'm asking about any opinion 14 referring to the fact that you have only seen you intend to offer in the MDL. a quantitative assessment of the weight of 15 15 16 A. Okay. So I will not be giving 16 particular components of scientific evidence 17 the causation analysis opinion, so that -- I 17 in evaluating epidemiological studies; is 18 will take that off the table. 18 that correct? 19 So I think my opinion is a 19 A. So that's what I typically see, 20 little stronger because I say that the 20 yes. And I don't know that -- I've never exposure to the perineal -- the talc by 21 seen it. But the typical approach would be 21 perineal application in women increases the 22 22 to use it there as opposed to using it in the 23 risk. So I'm not saying it's a possible 23 context of a human health risk assessment risk. I'm actually -- I believe that it 24 24 based on animal in vitro data.

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Q. All right. Are you familiar

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increases the risk. And I do believe that

Page 206 Page 208 1 with something called the Klimisch scoring 1 So, yes, if they stated they've 2 system? 2 done -- we'd have to pull the supplementary 3 A. I don't know if I am now. 3 materials out, but I recall them doing 4 scoring based on epi studies but not on 4 You'll need to show me what it is you're 5 the -- all of the animal studies that they 5 referring to. The name doesn't ring a bell, talk about. But we can pull it out and look. 6 6 7 7 Q. Okay. So it's not something I could be wrong. 8 that you've used in the past? 8 Q. Okay. Did you review the 9 A. No, not that I recall using. 9 supplementary material 7, 8 and 9? 10 Yes, I did, and we'd have to 10 Q. All right. pull them out because I don't recall the 11 A. Unless it has another name, and 11 12 that's why I'm asking you. 12 details. Q. All right. So if you have 13 Q. All right. We may take a look 13 actually -- it's the document in front of you 14 14 at those in a minute. 15 that we've already marked as Deposition 15 It talks about them classifying 16 Exhibit 5, I believe. 16 the animal and in vitro studies into four 17 Yes. 17 categories of reliability. A. 18 Do you see that? 18 Q. And that is the Taher study 19 that we were discussing and is cited by the 19 Yes. A. Q. So did you make any attempt, Health Canada risk assessment. 20 20 21 If you turn to page 5 -- well, 21 when you were reviewing the various studies actually beginning on page 4, do you see 2.2 in reaching your opinion about the potential 22 there is a section entitled "Literature 23 risk of talc in causing ovarian cancer, did 23 24 Search and Identification of Relevant 24 you make any attempt to separate out the 25 different pieces of evidence into categories 25 Nonhuman Studies"? Page 207 Page 209 of reliability like the authors of this paper 1 Do you see that? 1 2 A. Yes. 2 have done? 3 Q. And this is related to an 3 A. I didn't do it exactly the way 4 analysis that these authors performed on 4 they did it, but I certainly do do that as 5 5 potentially relevant animal and in vitro part of my screening. 6 I told you one of the б studies, correct? 7 7 Yes, that is true. characteristics or one of the assessments I Α. 8 All right. And it states here 8 make is whether I believe the data is 9 that "all retrieved studies were examined for 9 reliable data that I can -- that I can use in 10 relevance, reliability and overall quality 10 a weight of the evidence. So I make a -- and using the Klimisch scoring system." 11 when I talk about reliability, I'm talking 11 12 then about things such as I mentioned, peer 12 Do you see that? 13 review, whether or not there is statistical 13 Yes, I do see that. So I have seen that before. I just didn't -- I didn't 14 analysis, whether or not the study is 14 15 15 designed in a way that's consistent with recall it. 16 Q. Okay. And so would you agree 16 general principles of toxicology, control 17 that it is possible and in fact has been done 17 groups or not control groups. 18 in a study that you rely on to apply a 18 Those kinds of things I do -- I 19 quantitative scoring system to animal and in 19 do consider when I am assessing the use of a 20 vitro studies, particularly in the context of 20 study or not. 21 looking at the relationship between talc and 21 Q. Is it your testimony here today 22 that contained within your report that's 22 ovarian cancer? marked as Exhibit 4. I could find 23 Well, I didn't say it was 23 24 impossible. I said I don't believe it's 24 categorization of reliability of each of the 25 routine based on my experience. 25 pieces of scientific literature that you have

Page 210 Page 212 1 included in your weight of the evidence 1 reliance list? 2 analysis? Is that your testimony today? 2 A. I believe it was, yes. 3 A. No, that's not what I'm telling 3 Okay. And so for this one I 4 just want to direct your attention to the 4 you, no. 5 conclusion section -- well, let me ask you 5 Q. Okay. So you would agree that 6 6 you did not -- first of all, did you develop first: How does this document relate to the categories of reliability in which you 7 7 collection of documents with respect to 8 separated the particular scientific studies 8 Health Canada that you identified as relevant 9 into as part of your weight of the evidence 9 to your opinion? 10 10 analysis? A. It was one of the materials A. I do look at -- I do categorize 11 11 that they rely upon or they cite. That's the studies based upon my assessment of their 12 reason I pulled it. It was -- I pulled 12 13 reliability and their ability to be used to 13 documents that they provided on the website answer the question I'm asking, but I -- I 14 14 that were cited. 15 already told you, I didn't do it the way it's 15 Q. Okay. And if you could turn to 16 set out here. I didn't have these specific 16 page 11 of that document, there's a five categories, no. That's not what I did. 17 17 conclusion section. The first sentence of Q. Okay. Other than the CIR 2013 18 the third paragraph reads, "The given --18 19 publication, which you have said that you do 19 given the context-specific nature of each 20 not find reliable and you assign little 20 risk assessment and the diversity of tools 21 weight to it, can you point me to another 21 and criteria applicable, transparent 2.2 place in Exhibit 4 where you assign a 2.2 documentation of the specific application of specific category of weight that you have 23 the WOE approach is especially important." 23 24 given to a particular study that you include 24 Did I read that correctly? in your weight of the evidence analysis? 25 25 A. Yes, you did. Page 211 Page 213 1 A. If what you're asking me is do 1 Q. And is your understanding of 2 I make a specific statement next to each 2 WOE that it is weight of evidence? 3 study that I discuss about little weight or 3 Yes, that's correct. great weight, no, I don't do that, if that's 4 Do you agree with this 4 Q. 5 5 what you're asking me. statement? 6 Q. Okay. As part of the 6 A. In a regulatory context, I do 7 7 believe that that is true, because within the collection of documents that relate to Health 8 Canada that was provided to us as part of 8 regulatory context when they do the risk your new reliance list, did you review a 9 9 assessment, there's a need to understand why 10 document entitled weight of the evidence --10 decisions are made. So, absolutely, in a 11 or "Weight of evidence: General principles 11 regulatory context, I would agree that this and current applications of Health Canada"? 12 kind of transparency is even being adopted by 12 A. Yes, I've seen that. 13 EPA. 13 14 (Plunkett Exhibit 8 marked for 14 Q. And is it your opinion then 15 identification.) 15 that a different level of transparency is 16 QUESTIONS BY MS. BRANSCOME: 16 needed for expert testimony in court? 17 Q. All right. We will mark this 17 A. No, that's not what I'm saying. 18 as Plunkett Deposition Exhibit Number 8. 18 I'm saying that's a different process. And 19 All right. The document that I 19 that's what part of this process is. It's 20 just handed you that's marked as Plunkett 20 understanding the ability to provide a dialog 21 Deposition Exhibit Number 8, are you familiar 21 about what was done. with that document, Dr. Plunkett? 22 22 So as a result, this is 23 Yep, I've seen this before. 23 something that is common to the work that 24 Q. Is this listed among the new 24 I've done in the past. Even in a 25 materials that have been added to your 25 nonlitigation context with my regulatory

Page 214 Page 216 1 clients, doing a risk assessment doesn't 1 study. In other words, as I discussed many 2 necessarily involve the same level of detail 2 times in deposition, when you're talking 3 that a regulatory -- a regulator would apply 3 about doing a human health risk assessment, to the transparency of the assessment. Not 4 there's certain types of data that are most 4 to say that it couldn't be done, but it's 5 relevant. I mean, when they use the word 5 6 just -- I would say it's not necessarily "reliable" -- I don't know that many of these 6 7 7 studies have the same level of reliability as typical. 8 O. So this specifically refers to 8 far as peer review, but they're -- for 9 transparent documentation. 9 example, on the issue of migration, it's my 10 Do you see that? 10 opinion that the data from the human studies Yes. 11 is a more reliable or relevant source of 11 A. 12 information. And I've laid out why, because 12 Would you agree that the report that you have produced in the MDL does not 13 13 of differences in the anatomy, things like have documentation of the specific 14 14 that, with the data. 15 application of the weight of evidence 15 Q. Are you familiar with the term 16 approach? 16 "binning exercise"? 17 MS. PARFITT: Objection. 17 A. Yes, I am. And that is 18 Excuse me, objection. Form. 18 certainly something that I have used in other THE WITNESS: I disagree to an aspects of work that I have done. 19 19 20 extent because I did attempt to 20 Q. Did you do a binning exercise 21 provide in my report a description of 21 in rendering your opinions and what you've 22 the methods that I used and the 22 provided to us in the context of your 23 resources that I've relied upon for a 23 opinions in the MDL? 24 discussion of how those methods are 24 A. Yes, that's the exercise I 25 25 used. start with. I'm binning them into human, Page 215 Page 217 1 And then in addition to that, 1 animal, mechanistic, in vitro data. That's 2 2 I've attempted to lay out for you in the first bins. 3 my report a discussion of the pieces 3 In fact, in the copper work we 4 of evidence that I've relied upon, 4 did, that's what we did. We separated the including some -- for some of those --5 data into in vitro/only mechanistic 5 6 6 that's one of the reasons I got so information, animal studies, did we have 7 7 detailed in the section on migration human studies. 8 8 and providing you an analysis of each And we also looked at 9 of the papers that I relied upon and 9 studies -- we had a separate bin of exposures 10 what I thought was important within 10 like I do. I have studies that just address 11 them that led to my -- the formation 11 the issue of exposure potentially. 12 of my opinions. 12 So, yes, it's -- it's consistent with doing that. It's --13 So I disagree to some extent. 13 14 **QUESTIONS BY MS. BRANSCOME:** 14 essentially binning is just separating the 15 Q. Okay. Turning back to what 15 information into groups based on what Taher did in classifying different studies 16 16 questions those -- those data can answer. 17 into different categories of reliability. 17 Q. Okay. Have you ever -- do you 18 Have you done that type of analysis in the 18 ever separate them into bins based on the level of weight that you would give a 19 past where you have separated out different 19 particular study? 20 20 studies into different categories of weight or reliability as part of an overall 21 A. I do that when I'm analyzing 21 22 each of the studies within that group or that 22 analysis? 2.3 23 bin. That's what I do. I give them -- in my A. Well, I do that every time I do 24 24 weight -- in my analysis, I weigh those a weight of the evidence when I separate into 25 categories first based upon the type of 25 studies based upon my judgment on the

Page 218 Page 220 1 relevance, the reliability, the power of the 1 inflammation, cause ovarian cancer? 2 study, the statistical analysis that's done, 2 A. Because it doesn't change the 3 the inclusion in animal studies, in 3 phenotype of the cell. It has to -- the --4 5 particular, of controls. Those are all parts 4 and I discuss that. You have to -- you have 5 to set up a chronic inflammatory process that of that analysis that I do. So, yes, I do do 6 6 leads to changes within the cellular 7 And then in -- there have been 7 phenotype to go from a cell that is -- that 8 8 is -- is dividing normally to a cell that exercises that I've done in the past with 9 other individuals where we may have taken a 9 10 yellow sticky note and put down on top of it 10 So it's -- it's the same issue 11 animal data with exposure information, animal 11 that you address even in a study in animals. data without exposure information. That's 12 12 Why do not all animals exposed to -- exposed 13 the process that I'm doing when I am looking 13 to a chemical develop tumors. It's the idea that something has to be initiated beyond the 14 across the data. I'm separating those pieces 14 15 of data into groups and what types of 15 exposure or maybe beyond inflammation to lead 16 questions they can answer. 16 to the series of events. 17 So that is consistent with what 17 And so, yes, it's recognized that you can get inflammation, and 18 I do when I do a weight of analysis approach 18 inflammation can go down the road in becoming 19 in the work that I do in both nonlitigation 19 20 and litigation context. a carcinogenic process, or inflammation can 20 21 Q. Okay. But we have no specific 21 no longer -- can stay where it is. It 22 documentation of the different ratings that 22 doesn't progress beyond just a chronic 23 you gave the various pieces of evidence that 23 inflammatory process. you included in your weight of the evidence 24 Q. And so if you had a study that 24 demonstrated that a particular agent causes 25 analysis, aside from occasional references to 25 Page 219 Page 221 giving something less or more weight, 1 inflammation, you would need more information 1 2 2 in order to make the conclusion that that correct? 3 A. Well, I certainly -- I told you 3 agent can in fact cause cancer, correct? 4 I have not given numerical values that you're 4 MR. MEADOWS: Objection. 5 asking me, but I've attempted to do that when 5 THE WITNESS: You would look 6 I have described them in groups, when I talk 6 for more informative information, 7 7 about human versus animal versus in vitro. exactly, which is why, when I've 8 Because I've already told you, I believe, 8 talked about the individual it's my opinion that certain types of 9 9 constituents in the context of 10 information are more informative than others. 10 consistency on mechanism for cancer, 11 And so the more informative it is, the more I've pointed to documents where that 11 12 weight you're giving it in -- obviously in 12 information has been discussed. your analysis. 13 So like when I talk about 13 14 But it is a different exercise 14 asbestos or cobalt or I point to 15 than what is described here. And here I'm the -- for example, the IARC 15 16 pointing to Exhibit 8. And it's a different 16 assessment where they go through 17 exercise, obviously, than what a regulatory 17 that -- that discussion of the fact 18 body is required to do where they are trying that there's not just data showing 18 19 to come up with ways to increase the that a biologically plausible 19 transparency when no one can go and actually 20 mechanism may be inflammation, but 20 21 talk to each of the regulators individually 21 there's also data to show that that to understand what their thinking was. 22 22 can lead to tumor development as well. 23 Q. Okay. Returning to biological 23 QUESTIONS BY MS. BRANSCOME: 24 mechanism for a minute, why doesn't 24 Q. Okay. How does talc change the

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phenotype of the ovarian cell?

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inflammation generally, including chronic

Page 222 Page 224 1 So this is one of the details 1 in vitro or an animal experiment -- by which 2 we don't know, other than generally it's 2 you would expose either cells or animal to 3 changing the phenotype to go from a normal 3 tale with different constituent products to cell to a tumor cell. That is being 4 identify or separate out the individual 4 5 5 observed. When you find the presence of the effects of the components? Is that a study 6 6 tumor, that is what you're observing. that you could design as a toxicologist? 7 7 A. I think that would be difficult Q. Does pure talc with no other 8 constituent components, can it change the 8 to do, but I'm not saying impossible to do. 9 phenotype of an ovarian cell? 9 And here's the -- there are some very MR. MEADOWS: Objection. 10 specific considerations you'd have to put 10 THE WITNESS: So that's a into that design. 11 11 12 12 I would argue that some of that difficult question to answer with 13 certainty because of the fact that I 13 is already available, where we have studies 14 don't believe that we have assurance 14 that have looked at the dose-response effects 15 that any of the studies are done with 15 for toxicity with cobalt, with chromium, with 16 essentially pure talc. 16 asbestos. 17 However, in the studies that 17 When you get to asbestos and 18 talc, it's more problematic because then the 18 claim to have been done with pure 19 talc -- for example, the NTP study 19 question is what is -- what is it? What are 20 claims to have been done with pure 20 the specific characteristics in all the 21 talc. So if that is pure talc, truly 21 different studies of exactly what the 2.2 is, then that study is an example of 2.2 asbestos was versus exactly what the talc 23 evidence for the chronic inflammatory 23 24 process leading to preneoplastic 24 But I think you could attempt 25 lesions that are setting down the road 25 to do that, and then the question would be, Page 223 Page 225 1 mechanism towards cancer. 1 being able to use that data not so much to --2 So there are data out there. 2 not so much to identify a dose response for a 3 The problem you have, I believe, in 3 certain insult, but to look at the fact -the literature is whether or not, 4 look at potency differences across the 4 5 5 based on the discussion that is compounds. And then there's the issue of 6 6 then looking at additivity when you know you becoming apparent now with sensitivity 7 have a complex mixture. 7 and ability to take the natural 8 8 product and actually determine exactly So that could be done, but, 9 9 what's in it, that I don't think there again, it would be difficult to do based on 10 is the ability to assure that any --10 what we know about talc, being able to really 11 any of these studies with the samples 11 know that -- you would have to really be very of talc they're using is absolutely, 12 careful that what it is that you're looking 12 100 percent, only platy talc. I think 13 at is -- is not containing any of those 13 14 there's -- there's some concern about 14 things that we unfortunately know co-occur with constituents within the natural product. 15 that. But certainly you will take --15 16 you have to take what is discussed 16 But no one has done those 17 within the study as evidence from what 17 studies. I point that out. I haven't seen 18 they're claiming. 18 that study that you're asking for. I have 19 So many of the studies say we 19 not seen somebody do that. 20 used asbestos-free talc or platy --20 Q. And a study like that would be relevant in evaluating the potency of the 21 pure platy talc and we got a toxic 21 individual constituents and what might 22 22 response. 23 **OUESTIONS BY MS. BRANSCOME:** 23 actually be the driving factor for phenotypic 24 Q. Would it be possible to design 24 change, correct? 25 an experiment -- and now I'm talking about an 25 A. Not necessarily. I would argue

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that we already have an answer to that by looking at the data that's been collected on the complex mixture itself. So the issue would be why -- the question is what do you gain by being able to say that we're only pointing to this constituent or that constituent. That isn't what is occurring.

2.2

What people are exposed to is the complex mixture, not just each one of those individual components. To me this is not a case of asbestos-only exposure. This is a case of exposure to consumer products that are tale that may have within them at any given time -- and data indicates that there are substantial chance that asbestos may be in -- is in certain of these products.

But my opinions are not dependent on there being asbestos there at a particular level or copper there -- or, I'm sorry, cobalt there at a particular level because my opinions are based on the observations we have on the complex product as it exists.

Q. And you recognize that different types of talc and different talc

been linked to an inflammatory response.

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- Oxidative stress is often a triggering mechanism.
 - Q. Does the body have protective mechanisms that limit tissue damage from oxidative stress?
 - A. Yes, which is why not everybody that's exposed to any particular chemical is going to get cancer. Some people will respond better. Some cells will respond better. Some individuals in a population at one time in their life may respond better.
 - Q. You would agree that in vitro studies do not account for the body's natural defenses outside of what exists at the cellular level, correct?
 - A. Depends on the in vitro study that's being done and whether or not there is components added.

So I've seen studies done where they take cells and then add extra levels of glutathione to try to protect the cells from certain stressors that could lead to damage, but I agree with you that an isolated cell on its own is a different microenvironment than

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products have different constituent components in different amounts, correct?

A. Some can. I agree with that. That is true.

So if you're being broad, as in pharmaceutical-grade versus industrial-grade or chemical-grade, yeah, because they'll have a purity level assigned.

But as far as what the -- what the components are, it isn't always defined even specifically within that.

- Q. Okay. And does the presence of oxidative stress in a tissue indicate that cancer will develop in that tissue?
- A. Will definitively develop? Not -- I don't think you could say definitively develop, but it's certainly in the biologically plausible mechanism that's been understood to lead to chronic inflammation and also has been linked to cancer.

So that's the issue of not necessarily saying it has to be there, but it certainly is something that is observed routinely in cases where carcinogenesis has an intact tissue, which is a different environment than an intact animal, which is even different than an intact human being. Yes, they're all -- you look at those levels of evidence or those types of evidence differently, depending upon the end points you're collecting.

- Q. And so you would give lower weight to an in vitro study as compared to an in vivo study, for example?
- A. Depends on the question you're asking. I would give a lot of weight if the question is what do I know -- if I want to try to understand the biologically plausible mechanism, some of those in vitro studies are some of the most important, because it's the only ones that allow us to answer a question.

If the question is higher level about what is the evidence to show that there's an increased risk overall for cancer or a hazard for cancer, then certainly you need to have more than an in vitro study.

So as -- so on -- if you want to layer it up, obviously, if all you had was in vitro data, you'd have much less

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confidence in the conclusions you can draw unless you had some in vivo data. In vivo data is going to allow you to interpret the in vitro data.

So certainly there would be more weight given in that assessment to the fact that you had in vivo data.

- Q. And so when you made the statement that, for instance, you always give more weight to human data, is that true, or does that also depend?
- A. Well, it depends on whether you have human data. So if I have human data and I have a doubt, any doubts at all, about whether or not the exposure-response relationship would be affected by the way the animal studies are designed, then, yes, I would give more weight to the human studies.

In a case, however, such as inhalation exposure assessments where there -- it's much better, actually, to do an animal study where we can do a dose response across different sizes of particles and actually observe lesions as they develop over time, which is why I love -- I love the NTP

weight, but it could if you only had one crappy human study, one really badly designed

crappy human study, one really badly designed
 human study, and I had a GLP quality cancer
 bioassay then, absolutely. I mean, IARC does

bioassay then, absolutely. I mean, IARC does this. They look at that animal data and say,

"This one tells us -- answers the questions

we want to answer, and this very poorly
designed case series isn't going to allow us
to do that."

So you could, but I would say it's more the other issue, that you look at animal and human more on an equal basis if the relevance and the extrapolation can be done reliably.

And that's the question you have to ask, can I extrapolate from animals to humans in a reliable manner.

- Q. Okay. Would you agree that the response to cosmetic talc can vary depending on tissue type in the body?
- A. Yes, I would say that that is true, whether or not there's certain protective barriers in place, for example, yes.
 - Q. And so in order to draw

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93 study of interim sacrifices, looking at that issue. That data is very reliable in order to understand the risk of lung damage as compared to a human study where we don't have those serial time points, doses that are defined tightly.

So -- and the relevance between those kinds of initial lung injury in certain animals versus humans match fairly well.

That's my problem, though, in the case with the perineal exposure. I'm saying to you, because of the route of contact -- we need to be able to get it there to the tissue -- the human data is extremely important.

- Q. So is it fair to say that in some circumstances animal data gets more weight than human data and in other circumstances human data gets more weight than animal data? It is circumstance dependent?
- A. I would put it a different way. I would say in some cases animal data is weighted in a similar manner to human data. I don't necessarily say it would get more

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conclusions based on a study of one cell type's reaction to cosmetic talc to another, you would need to understand the differences in similarities between those two cell types, correct?

MS. PARFITT: Objection.
THE WITNESS: It's a different question. So you were asking me about -- I didn't think you were just asking about cells. I thought you were asking me about like routes of exposure, dermal versus inhalation. Those things differ.

Cell types may or may not.
That may or may not be true. Because if two cells -- two different cell types in the body share similar characteristics as far as the -- for example, if they're both epithelial cells or mesothelial cells, those type of cells you would expect to respond the same way.

But I would agree that, for example, a neuronal cell versus a GI cell versus a liver cell, there could

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Page 234 Page 236 1 be differences in how they would 1 Q. Okay. And in your -- in your report, as part of your risk assessment that 2 respond, yes, and so you would -- you 2 3 would look at those things 3 you did in the MDL -- this is paragraph 12 on 4 4 individually. page 8. 5 5 QUESTIONS BY MS. BRANSCOME: A. Yes, I'm there. 6 6 Okay. You state about O. And so it's important to 7 two-thirds of the way down the paragraph that 7 understand the differences and the 8 similarities between the different cell types 8 "weight of the evidence methods were critical 9 before drawing conclusions using studies from 9 to defining the literature that identified 10 different cell types? 10 the hazards of talc exposure as well as MS. PARFITT: Objection. defining the dose-response relationship 11 11 between talc exposure and the risk of adverse 12 MR. MEADOWS: Objection. 12 13 THE WITNESS: I certainly think 13 health effects." Did I read that correctly? 14 you should consider the cell types 14 15 that are being used and whether or not 15 A. You did. That's correct. 16 those cell types are ones that are 16 Q. All right. Is it your view 17 relevant to your risk assessment 17 that in the case you have reached an opinion question you're asking, yes. that defines the dose-response relationship 18 18 QUESTIONS BY MS. BRANSCOME: between talc exposure and the risk of ovarian 19 19 20 Q. Okay. You would agree as a 20 cancer? 21 toxicologist, dose is an important part of a 21 A. It depends what you mean by 2.2 toxicological analysis of an agent, correct? 2.2 define. I can tell you what I mean in this 23 A. If you're doing risk, yes. If 23 sentence, and maybe that would help you. 24 you're only doing hazard, it may not be as 24 Q. Dr. Plunkett, it is your important. It depends upon the question 25 25 report. And so I am asking you, using your Page 235 Page 237 1 you're asking about hazard. 1 own definition of "define," have you rendered 2 Do you want me to explain? 2 an opinion that defines the dose-response 3 Q. I do want you to explain the 3 relationship between talc exposure and the 4 difference between a risk analysis and a 4 risk of ovarian cancer? 5 5 hazard analysis. A. I have formed opinions about A. Okay. So in an initial hazard 6 the dose-response relationship generally, but 6 7 7 unfortunately -- I answered that question for analysis, if the question is, is there a 8 hazard associated with exposure, let's say, 8 you earlier when you asked me, I think, about 9 9 by inhalation, it may not matter whether it is there -- I don't know if you used the word 10 was a high dose or a low dose study. Both of 10 "threshold," but I did. 11 those can identify hazard. 11 So the available information 12 Then you ask the question: Is 12 doesn't allow us to identify an ultimate 13 there a dose-response relationship? That's 13 threshold, for example, in the case of women 14 the next step beyond hazard. 14 exposed to talc perineally and their -- and their development of ovarian cancer. 15 So hazard is -- to me is 15 16 identifying the end points that you're going 16 Instead, in defining the dose 17 to monitor for toxicity, sort of the target 17 response, what we can do with the data -- and 18 organs, those things, and so whether or not 18 that is what I attempted to do. This is 19 there's a dose-response study available, it 19 where you look at defining the dose response in the animal studies, which we can look at, 20 wouldn't be as important. 20 or defining dose response in cell studies, 21 But certainly when you go to 21 22 showing that as the dose increases, the that next step to assess risk, you'd like to 22 be able to see whether or not there is a 23 hazard and the risk increase. So risk 23 24 dose-response relationship in the effect that 24 actually you quantify. There's a certain 25 you're assessing. 25 response at this dose and a different

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1	response at the next dose, or have we	or that they may make a an
2	plateaued, that the responses are the same as	 author may make a statement, but I'm talking about looking this is weight of the evidence. I'm looking
3	dose increases.	talking about looking this is
4	So that, I did do that as part	weight of the evidence. I'm looking
5	of my assessment, trying to define the dose	across. And I'm saying, across the data, when I look at the human data versus the animal data, for example, versus in vitro studies, the in vitro studies and the animal studies allow
6	as far as how that linked to the responses in	data, when I look at the human data
7	each of the studies I looked at.	versus the animal data, for example,
8	Q. You would agree, though, that	8 versus in vitro studies, the in vitro
9	some studies did not show a dose relationship	9 studies and the animal studies allow
10	between talc and ovarian cancer or the	you to look at dose response for talc
11	clinical signs that were indicative of the	toxicity.
12	potential for development into ovarian	The even the animal studies
13	cancer, correct?	allow you to look at dose response for
14	MS. PARFITT: Objection.	development of precancerous lesions,
15	THE WITNESS: If you're talking	you're on the way to cancer, for
16	about the human data; is that what	example, in the NTP studies.
17	you're referring to? Or are you	And then in the human studies,
18	talking about all any of the data?	some of those studies are designed
19	QUESTIONS BY MS. BRANSCOME:	such that the authors could draw
20	Q. Any of the data.	conclusions about dose response and
21	A. So I would disagree on the	some are not.
22	animal data. I think on the animal data they	Even in some of the studies
23	often most of the animal studies I've	where they attempted to look at dose_
24	relied upon have looked at more than one dose	response, some of the authors indicate
25	or at least looked a no exposure versus a	they don't see an effect. So that is
	Page 239	Page 241
1		
1 2	dose, and most of them have looked at more	
2	dose, and most of them have looked at more than one dose.	
2	dose, and most of them have looked at more than one dose. In the case of the human	
2	dose, and most of them have looked at more than one dose. In the case of the human studies, unfortunately, some of those studies	
2	dose, and most of them have looked at more than one dose. In the case of the human studies, unfortunately, some of those studies were not designed to be able to define dose.	
2	dose, and most of them have looked at more than one dose. In the case of the human studies, unfortunately, some of those studies were not designed to be able to define dose. In other words, the questions weren't asked,	true. And part of that may be driven by the design of the study, the number of individuals in the study, the way that the questions were asked. There's limitations on the way that information is collected. If you want to look at each
	dose, and most of them have looked at more than one dose. In the case of the human studies, unfortunately, some of those studies were not designed to be able to define dose. In other words, the questions weren't asked, for example, of the individuals even in the	true. And part of that may be driven by the design of the study, the number of individuals in the study, the way that the questions were asked. There's limitations on the way that information is collected. If you want to look at each
2 3 4 5 6 7	dose, and most of them have looked at more than one dose. In the case of the human studies, unfortunately, some of those studies were not designed to be able to define dose. In other words, the questions weren't asked,	
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Page 242 Page 244 1 I think tale toxicity, I don't 1 is that you give them less weight because you 2 know if anybody has made the 2 believe that the individuals who conducted 3 comment -- I would doubt it -- that 3 the study had been paid by either a company 4 or agencies that had some investment in the 4 there is no dose response for toxic 5 5 effects of talc. outcome of the study; is that correct? 6 6 **QUESTIONS BY MS. BRANSCOME:** Is that my opinion? Q. Okay. You discuss in your 7 7 Q. Yes. 8 report -- wait a moment. It's in 8 A. For any particular study, 9 paragraph 58 on page 38. And I just want to 9 you'll need to show me what you're pointing 10 make sure I understood what you were citing 10 to. I do have opinions about some of the work by Drs. Huncharek and Muscat, yes. I 11 11 12 12 In paragraph 58 you state that think I address that specifically, and that 13 "It is important to remember that 13 has -- that's not so much to do with my 14 administration of even a single dose of talc 14 weight of the evidence; that has more to do 15 in animals has been shown to produce adverse 15 with transparency and what was being 16 effects locally at the site of the exposure." 16 disseminated to the public and disseminated 17 17 What are you referring to to the FDA as far as evaluations. 18 18 there? That's a different issue than 19 Acute doses. In other words, 19 the weight of -- the weight of -- the weight 20 in studies that have described installation 20 of the evidence assessment for risk. I think 21 of a single dose of talc in some form into a 21 those were separate. 22 tissue, that they are observing adverse 2.2 Q. So then I'll ask you that. 23 In doing your weight of the 23 responses. 24 An example of that may be 24 evidence analysis for risk, have you 25 the -- I think it's Hamilton. Is that the 25 discounted the weight that you've given to Page 243 Page 245 1 one where they stilled it into the ovaries 1 any particular piece of scientific evidence 2 with a single dose? 2 based off of potential affiliations of the 3 Q. So these are large-dose 3 authors? 4 exposures? 4 A. I certainly did with the CIR 5 5 A. Well, not all -review document. I've already told you that. 6 And that's because I have evidence that shows 6 Q. Or are they, I should say? 7 7 it's not just an affiliation issue, but it's I don't know that they all are, 8 8 no. There are -- there are -- I don't think actually -- it's more -- it's more important 9 9 I have attempted to quantify large in this than that. 10 sentence. 10 Q. Are there any other examples? 11 What I'm stating here is not an 11 A. I think that's the only one issue of large versus small. It's an issue right now as I sit here that I can tell you 12 12 of the fact that there are toxic effects with 13 that I had identified as carrying little 13 single exposures. And I'm just making the 14 weight because of an issue of either 14 15 comment -- this has to do with hazard, right? 15 authorship or input in the way it was 16 It's the idea even a single dose -- or a 16 described. 17 single exposure you can get irritant, 17 There are certainly studies 18 inflammatory reactions at the site of 18 within my weight of the evidence evaluation, 19 exposure. And that's all I'm trying to say. 19 some of which were performed by industry. I certainly look at that issue, but unless I 20 That's why I'm citing as reviewed by EPA. I 20 21 believe EPA even makes a very similar 21 have -- have a reason to believe that there's 22 22 an inherent bias based on something I know, statement. 23 they go into the weight of the evidence 23 Okay. Do you take into 24 account -- there are some studies for 24 without making a correction for that. 25 which -- at least my reading of your report 25 In many cases that I work in

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Page 246 Page 248 1 litigation, I will find situations like the 1 tested, that he reports are Johnson's baby 2 situation here with Huncharek and Muscat 2 powder, did you also consider the work that 3 where I have, for example -- I think this 3 was done by experts that have been retained 4 4 came up in the Risperdal litigation for me. on behalf of the defendants to characterize 5 5 It's the idea that there was a series of the components of Johnson's baby powder? Do 6 6 papers put out by an individual investigator you give them equal weight? 7 where documents that I could get access to 7 A. So I haven't seen a variety of 8 8 show me that indeed their analysis was not the documents that you're talking about, 9 done by them but it was ghostwritten by 9 so -- because I have not worked in the 10 somebody else. So that gives me pause, 10 litigation cases that have involved asbestos 11 although I would never have known that unless 11 only. So -- which I think is where those 12 12 I had access to internal documents. documents are. 13 So initial weight of the 13 In the litigation I -- in the 14 evidence I did not discount it, but then I 14 litigation I worked in, I am aware of what 15 went back and had to reevaluate the role 15 other experts on both sides have said. I 16 those studies played in my overall 16 don't believe I've seen an analysis from a 17 17 assessment. defense expert that is -- that is like 18 18 Dr. Longo's, at least in the litigation I've Q. Do you take into account in any 19 way in evaluating the weight of a study if it 19 worked in. Certainly I would consider that 20 is conducted by someone who serves as an 20 and look at that if it's available, and I 21 expert on behalf of the plaintiffs in the 21 would consider it. 22 active litigation? 22 I would point out, Dr. Longo's 23 analysis is not the piece of evidence that 23 A. It would be the same -- same 24 issue. I certainly consider it as part of 24 you start with, though. You start with what 25 what I look at, but just like if they were an 25 I discuss in the published literature first, Page 247 Page 249 1 expert for the defense versus an expert for 1 because there are published documents out 2 the plaintiff, you judge that information 2 there in the literature that describe exactly 3 based on what you know. And if I don't have 3 what Dr. Longo is now describing. 4 information to discount it, I will not 4 What published documents are Q. 5 5 discount it. those? 6 6 Those are Dr. Blount's reports But absolutely, I understand. 7 7 Just as people we all -- look at some of the in 1991, which is before the litigation came 8 things I've published where I have said my 8 about, is my understanding. 9 9 work was sponsored by the American Chemistry There's also -- there's five or 10 Council. You know, people -- that's why you 10 six. I can tell you the paragraph. disclose the conflicts. You put it there so 11 Q. For Johnson's baby powder, I 11 12 would be interested in that, yes. 12 people can weigh it if they want, but it 13 13 doesn't mean you discount the work A. So I -- I'll have to look and 14 see if it's Johnson's baby powder only, but 14 automatically. 15 certainly there is other evidence on the 15 And so I think for any paper, 16 plaintiff, defense, whoever it is that's 16 issue of asbestos contamination and 17 writing it, you need to consider it based on 17 specifically in talc. the information you have. And if you believe 18 So I -- you want me to find the 18 19 paragraph for you? 19 that you have information to indicate that 20 Q. Please. If you think there is there's some issue with the reliability of 20 21 published literature documenting asbestos in 21 the analysis, then absolutely you consider 22 Johnson's baby powder, I would like to see 22 23 Q. So, for example, when you rely 23 that. 24 on Dr. Longo's characterization of the 24 A. So this is my paragraph 32. 25 25 And I'd have to pull each of these articles constituent components in samples that he has

Page 250 Page 252 1 out because I don't recall what each of them 1 look. 2 says. But I'm pointing to Paoletti, Blount, 2 Q. Have you reviewed Dr. Blount's 3 Mattenklott, Moon, Gordon, Anderson, Rohl, 3 deposition? Pooley and Rowlands, Blejer and Arlon, 4 4 A. I have reviewed a -- something 5 5 Cralley, Millman. by Dr. Blount. Whether it was trial 6 And then I cite -- and then of testimony or deposition, I have seen 6 7 7 something, yes, that she has said regarding course the next piece of evidence is there 8 are actually documents from J&J and Imerys 8 this issue. 9 that show detection of asbestos or 9 O. To the extent that there is asbestos-like minerals in talc. 10 confusion about whether or not a sample 10 11 tested by Dr. Blount is in fact Johnson's 11 Q. As you sit here today, can you baby powder, would you reduce the weight that identify which of these published articles 12 12 13 that you list in paragraph 32 relate to 13 you give that particular piece of evidence in Johnson's baby powder? evaluating whether asbestos has been present 14 14 15 A. I would have to pull them to 15 in Johnson's baby powder? 16 16 MS. PARFITT: Objection. Form. answer that. MR. MEADOWS: Objection. 17 17 Q. Okay. 18 THE WITNESS: I don't know 18 As I sit here, I'd have to pull A. them. But I would refer you -- I know at 19 19 reduce the weight because -- because 20 least some of them do based on the statement 20 there's -- there are plenty of 21 I've made, but... 21 documents here that talk about that. 2.2 22 I would consider it --Q. So you did not make an attempt in this paper to identify which products were 23 23 certainly it would -- it's not so much 24 being analyzed in these specific articles. 24 weight. It's a different bin. We'll It's not indicated on the face of this 25 25 call it a bin, a different bin of Page 251 Page 253 1 paragraph, correct? 1 information. There's information on 2 A. I don't tell you on the face, 2 talc powders generally, and then 3 but you if read the sentence I said, "When 3 there's some information that's commercially available, talcum powder 4 specific to certain body powders. 4 5 5 products were analyzed, including powders So certainly -- would I pay sold by Johnson & Johnson. The data has 6 attention if they identified it? Yes. 6 7 shown that the powders contained varied 7 But in the statement I'm making 8 levels" -- and I'm saying "fibers," so it's 8 here, I'm not claiming that every one just asbestos -- "including fibers that 9 9 of these is relating to just the 10 stated to be asbestos." 10 powder sold by Johnson & Johnson. 11 So to tell you which of those, 11 This is across the available I'd have to pull them. And I apologize, I 12 12 information that's public and then didn't bring them all with me. 13 also the information that's available 13 14 Q. Have you been provided --14 in the files of Johnson & Johnson. you're aware that Dr. Blount's paper does not 15 15 **QUESTIONS BY MS. BRANSCOME:** 16 identify Johnson's baby powder in the face of 16 Q. What is your definition of 17 the article, correct? 17 asbestos? 18 A. I believe that's true. You'd 18 My definition of asbestos is 19 have to go to her deposition, I believe, 19 exactly what the different documents describe 20 where she's given -- where she discusses what 20 it typically. It's a fibrous mineral, the source of that was, and maybe even a -typically. It occurs in a variety of 21 21 different forms. Most of the times they'll there may even be a separate document, 22 22 23 actually, not a deposition, that was -- that 23 say "asbestos." Sometimes they'll say "chrysotile." Sometimes they'll say 24 was in the files of Johnson & Johnson that 24 25 goes along with that, but I'd have to go 25 "tremolite." Sometimes they'll say

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Page 254 Page 256 1 "anthophyllite." Those are the three most 1 A. Has to do with the fact that we 2 common ones I see. But those are all mineral 2 have a complex mixture that has multiple 3 forms of asbestos. 3 carcinogenic substances. 4 So just like IARC puts those And asbestos is important from 4 5 5 all within one bin, I'm putting those all in the aspect of the way that it has been 6 6 one bin because they have a similar toxicity assessed even by regulatory bodies, the idea 7 profile. 7 that even very low levels of fibers pose a 8 Q. Is it your view that each of 8 cancer hazard and a cancer risk in 9 the different types of asbestos has the same 9 individuals have been shown to be toxicity profile? 10 10 carcinogenic. A. They all have the same ability 11 11 So that's what I'm saying about to cause cancer, but they have different 12 potency of asbestos is different than potency 12 13 potencies. So they do have -- there will be 13 of some other carcinogens that you might look some differences in the dose response and the 14 14 at. But the importance of it is it's a 15 potency of them, but certainly they've all 15 complex mixture, talc, body powders, a 16 been linked as being carcinogens by IARC. 16 complex mixture that includes constituents 17 And I would agree, when you 17 that are known human carcinogens as well as look at their data, there is data and 18 18 some that are -- been ranked other ways by 19 evidence to indicate that. 19 regulatory bodies. 20 20 Q. If Johnson's talcum powder Q. Which type of asbestos is the 21 most potent? 21 products do not contain asbestos, does that 2.2 2.2 change your opinion with respect to the risk A. For which end point? For lung 23 cancer? I believe chrysotile is. For other 23 they pose with respect to ovarian cancer? 24 end points, I'd have to go look. I mean, 24 A. No, and I think that was very 25 chrysotile is the sharp -- is the sharp --25 clear if you looked at my first report. So Page 255 Page 257 1 the sharded-type structure. 1 even -- there's -- I don't think in any of my 2 But there's data on fibrous --2 reports I've opined that without looking at 3 the fiber -- the fibrous forms of asbestos 3 the complex mixture that we wouldn't be here. rather than the -- or the amphibole forms of 4 In other words, I have not 4 5 5 asbestos as opposed to chrysotile, which is opined that if it doesn't have -- if it 6 6 the serpentine form. doesn't have asbestos, it's not a risk. I 7 7 Q. Do you consider yourself an have not opined that, and I don't believe 8 8 expert in asbestos? that, because I think there is independent 9 9 A. Not in -risk for the fact that we have a complex 10 MS. PARFITT: Objection. 10 mixture of talc that has been tested and 11 shown to be carcinogenic. 11 THE WITNESS: Not the geology 12 12 It's my opinion, I told you -of asbestos, no. 13 maybe it wasn't you. I may have told this I have expertise in toxicology 13 14 yesterday, I'm sorry, to Mr. Smith that I 14 as it relates to interpretation of the believe that there is evidence to show that 15 15 data related to asbestos. I have 16 never give -- given testimony in a 16 there is a significant exposure to asbestos case on asbestos, but it's something 17 based on the data that's been collected. 17 18 But certainly, you know, in 18 I've studied in the past in my work as 19 some -- the data has shown that in the assays a toxicologist, not as a testifying 19 20 expert. that have been done or the analyses that have 20 21 been done that you can't say that talc is 21 QUESTIONS BY MS. BRANSCOME: 22 asbestos-free. 22 Q. What role does your analysis of 23 23 the possibility that there may be asbestos in Q. Well, so --24 Johnson's talcum powder products play in your 24 A. So --25 -- the question I have risk assessment in the MDL? 25

Page 258 Page 260 1 specifically relates to ovarian cancer. 1 asbestos above background through the 2 Is it your view that through an 2 perineal use of Johnson's talcum powder 3 exposure route that is relevant for ovarian 3 products? 4 MR. MEADOWS: Objection. 4 cancer, that the use of Johnson's talcum 5 products involve a substantial exposure to 5 MS. PARFITT: Objection. 6 6 THE WITNESS: I don't think asbestos? 7 7 A. I believe based on the use of that's the opinion I have formed to 8 the products that -- where the data has been 8 date, but certainly the opinion I have 9 collected that there would be a substantial 9 formed is that the data I have seen 10 indicates that you can't separate out 10 exposure to asbestos, regardless of how you're exposed, perineal -- perineally or by 11 talc without asbestos versus talc with 11 12 12 asbestos in the information that's inhalation. 13 What is your basis for reaching 13 been collected. Because there's --O. that conclusion? 14 all -- the information that's been 14 15 A. It's looking at the number of 15 collected has shown there's no 16 fibers that have been detected in the 16 evidence that asbestos-free talc is 17 17 products, in looking at the -- the widespread available. nature of the presence of asbestos fiber --18 If by asking that question 18 19 you're trying to say that it's the 19 asbestos in the talcum powder products and 20 asbestos alone that's causing the 20 the fact that even though it's at a very low level by their -- their level of detection, 21 cancer, that is not my opinion. So 21 2.2 again, can't be said to be asbestos-free. 22 that is when the dose issue would 23 become very important for asbestos. 23 So regardless of whether it's 24 QUESTIONS BY MS. BRANSCOME: 24 talc that's being applied perineally or a 25 Q. Okay. talc that you're inhaling while you're 25 Page 259 Page 261 1 applying it perineally, the fibers are still 1 So that's -- so that's a 2 going to be present within that talc. 2 different question I have not answered. 3 Q. Have you or anyone done an 3 And in reaching your opinion analysis of the dose of asbestos to which 4 that there is no evidence that asbestos-free 4 5 5 someone might be exposed perineally? talc exists, you have not been provided with 6 the reports by the defense experts, including 6 A. I haven't done a specific 7 7 Dr. Matthew Sanchez, analyzing Johnson's calculation, no. 8 8 talcum powder products for the presence or Q. Has anyone done that 9 calculation? 9 absence of asbestos, correct? 10 MS. PARFITT: Objection. Form. 10 MS. PARFITT: Objection. Form. I think you're aware that the 11 **OUESTIONS BY MS. BRANSCOME:** 11 12 12 Q. That you have seen? MDL expert reports have not yet been 13 MS. PARFITT: Objection. 13 provided to us. THE WITNESS: I'm trying to 14 14 MS. BRANSCOME: Yeah. remember whether I saw that done in 15 15 MS. PARFITT: I'm just making a 16 any of the documents related to 16 point. 17 Dr. Longo. 17 THE WITNESS: I have not seen a 18 18 report by Dr. Sanchez. I assume I I don't know. I'd have to go 19 19 will, because typically after -- later look. 20 in the litigation, once all experts **OUESTIONS BY MS. BRANSCOME:** 20 have been deposed or revealed, I'm 21 Okay. So as you sit here 21 22 today, can you give an opinion to a 22 usually given defense expert reports and their deposition testimony. So I 23 scientific degree of certainty, reasonable 23 24 degree of scientific certainty, that an 24 expect to see that; I just haven't 25 individual would be exposed to a dose of 25 seen it yet.

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Page 262 Page 264 1 QUESTIONS BY MS. BRANSCOME: 1 application for any of the heavy metals. So 2 Q. And you haven't seen it in any 2 the three that I've mentioned, no, I have not 3 of the cases in which you've rendered an 3 done that calculation. opinion, correct, not just the MDL? 4 4 Q. You would agree, based on your 5 A. Well, none of the cases that I 5 training and experience as a toxicologist, have worked in have involved the issue of 6 that in order for an agent -- and we can talk 6 7 looking for asbestos exposure. 7 specifically about a metal -- to present a 8 The cases I have worked on have 8 risk of cancer it needs to be bioaccessible, 9 been talking about talc exposure that may 9 correct? 10 include asbestos as a constituent, but it 10 A. If by bioaccessible you are not 11 wasn't focused on asbestos exposure. limiting that definition to solubilized into 11 the blood and carried systematically, yes, I 12 So, no, none of the cases I 12 would agree with that. Bioaccessible meaning 13 worked on have provided testimony in that 13 it has to be in a form that can somehow 14 area. 14 15 You understand what I'm saying? 15 interact with the tissue, yes, I agree with 16 Q. Let me just make it clear. You 16 that. But it could be as simple as tissue have not, in any of the cases in which you contact versus needing to be solubilized. 17 17 have offered opinions with respect to the Q. Okay. Is silica bioaccessible? 18 18 contents of talc, been provided with an A. It depends on the form of the 19 19 20 expert report or testimony by Dr. Sanchez 20 silica. So silica particles can be 21 about what he did or did not find in 21 bioaccessible if inhaled and found on the 22 Johnson's talcum powder products with respect 22 surface of the lung. That can cause injury to asbestos? 23 at the site of the lung. So that's an 23 24 MS. PARFITT: Objection. Form. 24 accessibility to that particular tissue that THE WITNESS: So I can't tell 25 25 it contacts. Page 263 Page 265 1 you that I have not. I don't recall 1 Q. We talked earlier -- it's 2 it. That's all I can say. I don't 2 somewhat related to bioaccessibility, but we 3 recall that name. 3 talked about the way in which different QUESTIONS BY MS. BRANSCOME: 4 particles might move specifically through the 4 5 5 Q. It's certainly not something genital tract in women. you discuss in your report, correct? 6 6 Do you recall that? 7 7 A. No. I do not. And I don't know Yes. A general discussion. A. 8 that it's in my reliance materials. That's 8 Q. 9 why I'd ask you to look there, because if 9 And when you testified that 10 it's in my reliance materials, then I've seen 10 starch and talc might not move at the same 11 11 rate, do you have an opinion as to which it. 12 might move more quickly through the tract? 12 Q. Okay. And I mean big reliance I haven't formed that opinion, 13 13 14 material list, not my reference list. 14 no. Q. All right. With respect to the 15 15 Okay. And do both talc and other potential constituents of talc, have 16 16 starch particles remain in the body for the 17 you done any analysis to provide an answer as 17 same length of time? 18 to how much -- what dose of chromium, for 18 A. I haven't done an analysis to 19 example, an individual might be exposed to 19 see if the data tells us what the -- what the differences might be. I would expect there 20 through the perineal use of Johnson's talcum 20 21 powder products over a lifetime? 21 to be differences, which is what I told you 22 22 A. No, and I have -- well, I know earlier, because I would expect the starch to 23 it's a separate deposition. We discussed be able to be solubilized, where I would not 23 24 this yesterday. No, I have not done a -- a 24 necessarily expect the talc to act in that 25 calculation of a potential dose with perineal 25 same manner.

Page 266 Page 268 1 Q. Is cornstarch capable of 1 only three heavy metals: chromium, cobalt 2 causing an inflammatory process? 2 and nickel. 3 A. It can. It is -- but it is --3 Do you see that? 4 4 it's a different level of risk for A. Yes. 5 5 inflammatory responses than is talc, just by Q. Why did you remove three of the б 6 its chemical nature. heavy metals? 7 7 Q. Have you done an analysis in A. It's not so much removing. 8 your report that examines the differences 8 Those three heavy metals that I focused on in 9 between the inflammatory response that can be 9 my MDL report are ones that have been talked 10 triggered by talc as opposed to cornstarch? 10 about with a similar mechanism of action as 11 A. I haven't analyzed inflammatory 11 far as irritation and biologic -- biologic 12 response. Instead, what I've done is done a 12 plausibility mechanism being irritation and 13 comparison of what the toxicity -- the 13 inflammation. 14 differences in the toxicity potential have 14 So that's why I focus on those 15 been described in medical literature, and I 15 three, which may not -- which is not 16 cite -- I have a paragraph where I cite to 16 necessarily the case for some of the others, 17 some sources that talk about the differences 17 even though they're also -- have a in the toxicity potential or biocompatibility 18 carcinogenic hazard, pose a risk. 18 19 of starch versus talc. 19 Q. So in your -- as part of your 20 20 risk assessment that you performed in the Q. Now, I had a question about 21 your supplemental report that was marked as 21 MDL, are you offering the opinion that to the 22 Exhibit 3 to the deposition. 22 extent they exist in any of the Johnson 23 At paragraph 67... 23 talcum powder products, that arsenic, lead --24 Okay. 24 A. Cadmium. A. 25 You identify here six heavy 25 -- and cadmium play any role in Page 267 Page 269 1 metals - arsenic, chromium, lead, cobalt, 1 the risk of developing ovarian cancer? 2 cadmium and nickel - that in your 2 A. That is not an opinion that I 3 supplemental report dated August 29, 2018, 3 would be offering in the MDL. you say have been reported across lots of 4 Q. Okay. Now, you talk about 4 5 5 talc powders. these heavy metals having been classified by 6 6 different agencies as either known probable Do you see that? 7 or possible human carcinogens, correct? 7 A. Are you in -- now you're in my MDL report or here? 8 8 You're in my MDL report again? A. 9 9 Q. No. O. Oh, yes. 10 A. Oh, so where are you? I'm 10 A. Okay. I'm sorry. Okay. Let 11 11 me get there. sorry. 12 12 Same report. It's the sentence Yeah, I do have that Q. that begins at the bottom of page 6. 13 discussion. I'm just trying to find it. 13 Okay. Hold on. 14 14 Q. Sure. A. 15 About that they have varied at 15 Okay. Yes, I'm there. A. 16 the levels --16 Is it your view, based on your 17 Yes. So you identify six 17 expertise, that because a compound can cause O. 18 different types of heavy metals. 18 one type of cancer, it can cause all types of 19 Do you see that there? 19 cancer? 20 Yes, I do. 20 No, not necessarily. It A. depends on the -- well, it depends on a 21 Q. Okay. And the question I had 21 couple of things. It depends on what's been 22 for you was that in your report in the MDL, 22 23 studied. Have all types of cancer even been 23 if you look at paragraph 36 --24 A. Yes. 24 studied. And then it also -- it also depends 25 -- you identify -- you identify 25 upon, I believe, the route of exposure as

Page 270 Page 272 1 well. So can it get to where it could cause 1 you can extrapolate with scientific basis 2 that, could it distribute there. And then in 2 from one type of cancer cause to ovarian 3 addition to that, what data has been 3 cancer with respect to the heavy metals 4 4 specifically? collected. Is there enough data, for 5 A. Well, I haven't attempted to 5 example, to show that there's extrapolation 6 that, because I haven't attempted to define a 6 from animals to humans in the types of tumors or is it -- or if we have good human data, 7 independent risk for each of those metals 7 8 8 then we would focus on the types of cancers individually. 9 that you're seeing in humans, for example. 9 The issue -- the issue I have 10 Q. Okay. But you recognize even 10 with those metals is -- there's a paragraph where there is complete data some compounds 11 here where I talk about pathogenesis of 11 12 can cause one type of cancer and they are 12 carcinogenesis, where I talk about different 13 incapable of causing another type, correct? 13 stages of cancer development and the fact MS. PARFITT: Objection. Form. 14 that inflammatory responses may be operating 14 15 THE WITNESS: I don't know 15 at all those different stages. 16 about incapable, but I would agree 16 So the issue is you have that you certainly would see -- you 17 17 potential -- you have compounds that are could potentially see different 18 known to produce cancer or have been shown to 18 have a potential risk of cancer. They share 19 19 observations. 20 a similar mechanism to talc, so as a result 20 If you're talking about animals 21 versus humans, or are you talking 21 of that, they factor into your risk 2.2 about --22 assessment as far as there being an exposure QUESTIONS BY MS. BRANSCOME: 23 23 to a mixture. 24 24 But on the issue of ovarian Q. If humans. 25 25 Based on what you had seen in cancer, I'm looking at the data that's been Page 271 Page 273 1 the animals; is that what you're asking me? 1 collected on talc itself, which would be talc 2 O. Yes. 2 with the constituents that could include the 3 A. Yes. So, yes, there is not 3 metals. But certainly I'm not saying that it always a one-to-one concordance. So that's 4 is -- without the presence of one or the 4 5 5 why -- that's why I made the comment that other of these there would be no risk of 6 it's important to have some human data or 6 ovarian cancer. I'm not saying that either. 7 7 experience, so that you can put in context So my question is, though, can 8 8 the data you collected in animals. you point me either to scientific literature 9 I would say to you there are 9 directly documenting that these heavy metals 10 certain kinds of tumors in animals, for 10 can cause ovarian cancer or to scientific 11 example, that are shown to be not relevant at 11 literature that enables you to extrapolate 12 12 all to human risk assessment. Like four from the types of cancer that they are known 13 13 or believed to cause to ovarian cancer? stomach tumors in rats is an example. I've 14 14 A. So I -- on the issue of can I dealt with that one a lot. 15 Q. What types of cancer -- type or 15 point you to the data on ovarian cancer, I'd 16 types of cancer are the basis for the 16 have to go back. I can't answer that without 17 classification of chromium as a known human 17 looking at the assessments. 18 carcinogen by IARC? 18 But on the other -- second 19 A. So I have to pull it out, but I 19 question you asked me, that's the question I 20 believe that there may be some GI cancers and 20 was just trying to answer before. It's the 21 21 maybe some skin cancers, but I'm not sure. idea that regardless of where the cancer is 22 22 I've got it pull it out. It's been a while developing, the fact that these compounds 23 23 have the ability to stimulate similar toxic since I've looked at it. 24 Q. Okay. Have you done an 24 responses in tissues could lead to a --

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setting up a situation where the -- where the

25

25

analysis to evaluate whether or not the types

Page 274 Page 276 1 tissue is primed for cancer development. 1 So, again, that's what I'm 2 Q. And do you have --2 pointing to and why I have cited the data. 3 A. And so that --3 Q. Now, you talked about -- when 4 4 Q. Sorry. we were discussing mechanism, you said that 5 inflammation alone is not necessarily 5 A. And that has to do with the 6 6 basic science of carcinogenesis when you look sufficient to cause cancer, correct? at underlying mechanisms, especially with 7 7 A. Yes, I did. 8 8 tissue contact, direct tissue contact, with Q. All right. Do you have 9 irritants or inflammatory processes. 9 scientific studies that show that any of the 10 But I would -- I am not -- I 10 heavy metals or the fragrance constituents have not formed the opinion, again, that with that you identify as potential carcinogens 11 11 12 create -- generate phenotypic changes like 12 or without either one of these that I would 13 expect ovarian cancer to be the target. I'm 13 vou discussed were next for the formation of 14 14 saying that ovarian cancer risk is increased cancer? 15 based on exposure to talc, which includes a 15 A. I believe that data is 16 variety of constituents. 16 available on nickel. I need to go back and Q. Okay. And do you cite anywhere 17 17 look at chromium and cobalt, but I do believe in your report to studies documenting -- I 18 with nickel you'll find similar data on 18 know you said you'd need to go look at them, 19 19 tissue irritation and inflammatory processes. but I'm asking if it's in your report 20 Nickel is also a sensitizer, so 20 21 anywhere a discussion of any studies showing 21 it has interaction with the immune system, so 22 that the particular heavy metals that you 2.2 I do believe that for nickel you can find 23 cite as potential constituents of Johnson & 23 some of that data. Johnson's products have been demonstrated to 24 24 Q. Okay. But as you sit here increase a risk for ovarian cancer on their 25 25 today, can you point me into any of that Page 275 Page 277 1 own? 1 that's discussed in your report? 2 So, no, I haven't addressed 2 A. No specific discussion other 3 that in my report. And again, I think that's 3 than, again, all -- the IARC -- I'm citing to 4 inconsistent with the way I'm using these 4 the IARC assessments, and the IARC 5 5 data. But that's fine. I mean, no, I assessments for each of those discuss 6 haven't done a specific assessment of ovarian 6 carcinogenesis and a biologically plausible 7 7 mechanism being linked to the ability of cancer risk with each of those metals 8 8 individually. these compounds to induce oxidative stress 9 9 Q. I would ask the same questions and/or inflammatory processes. Q. Okay. In your opinion, you 10 for the different fragrance constituents that 10 11 you allege in your report are potential 11 talk about the mixture of constituents that 12 12 carcinogens. are involved in talc. 13 13 Have you done any analysis, and Have you done any analysis to can you point me to any scientific studies 14 look at how the different constituents 14 that establish that those particular 15 15 interact with each other? 16 compounds are capable of causing ovarian 16 A. Well, yes, that's my issue at cancer? 17 17 looking at underlying mechanism. 18 A. No, I haven't done that 18 But are you asking me -- I 19 analysis, but, again, general principles of 19 certainly don't have a -- the only studies 20 toxicology and cancer risk assessment, when 20 that I have to rely upon on the interaction 21 21 you look at the presence of multiple -of the mixture is the actual studies on the 22 excuse me, multiple carcinogens with similar 22 powders themselves, where we know that the 23 mechanisms of action, you would assume in powders contain constituents other than just 23 24 your risk assessment that those risks could 24 platy talc. 25 be additive. 25 Q. Okay. And do the constituents

Page 278 Page 280 1 need to have the same underlying potential 1 So those two -- we'd have human data 2 carcinogenic mechanism for them to have an 2 to show that. 3 additive effect? 3 But on the issue of cobalt, it 4 A. By general principles of 4 may only be -- I need to go back and 5 toxicology, yes, you look at mode -- mode of 5 look, but it may indeed just be animal action or mechanism of action before you 6 6 7 apply that additivity principle to the cancer 7 **OUESTIONS BY MS. BRANSCOME:** 8 risk assessment. 8 Q. And so your basis for that 9 Q. And so as you sit here, you 9 would be the IARC classification? 10 10 Is that where I would go to believe there have been scientific look if I wanted to look at it after this 11 documentation that nickel might operate 11 12 through the same biological mechanism as you 12 deposition? 13 purport talc to operate, but you're not sure 13 A. I'd go to the IARC reviews. about the other heavy metals or the fragrance 14 14 I'd go to those three which I believe I have 15 constituents: is that correct? 15 cited down here for you and given you where 16 MS. PARFITT: Objection. 16 to go to find them. 17 THE WITNESS: For the fragrance 17 Q. Okay. You discuss in your constituents, I'd definitely have to report -- and if you'd like to reference it, 18 18 19 pull because I haven't looked at that 19 it's paragraph 69 on page 47 -- the concept 20 individual assessment in a while. 20 of genotoxic and nongenotoxic carcinogens. 21 For these three, what I do know 21 Do you recall that? 22 is that they do share the ability to 2.2 Yes. A. at least induce oxidative stress. 23 23 And as you sit here today, is 24 What I can't recall for 24 it your opinion that talc is more likely a 25 25 nongenotoxic carcinogen? chromium and for cobalt is whether Page 279 Page 281 1 they're taking it the next step from 1 A. As the direct insult, yes. And 2 oxidative stress to inflammatory 2 I would like to -- I would like to point out 3 process. I believe that they do, but 3 that in the literature -- the reason I have I'd have to check, whereas I know 4 this paragraph here is because in the 4 5 5 nickel has been shown to lead to an literature in the past, in the area of 6 6 chemicals, it's been -- toxicologists have inflammatory process after oxidative 7 7 stress has been induced. attempted to put two bins, direct genotoxic 8 8 QUESTIONS BY MS. BRANSCOME: insult versus nondirect genotoxic. It 9 And you would agree, even more 9 doesn't mean you can't get a genotoxic event 10 than requiring an inflammatory process, you 10 after the initiation. 11 would actually have to see that these 11 So I want to make sure you 12 understand that. I'm not saying that there 12 compounds can generate phenotypic changes, 13 13 is no possibility of this chemical in its -correct? 14 MS. PARFITT: Objection. 14 in its process of inducing cancer leading to THE WITNESS: Well, we know 15 15 indirect genotoxicity, but I'm talking about 16 they do because they've been shown to 16 the direct mechanism at the site of the cell. 17 be carcinogenic. If you've been shown 17 So talc, for example, has been 18 to be carcinogenic, you've done a 18 shown to not be genotoxic in cells. And so 19 phenotypic change in the cell from a 19 that's why I believe, then, when I look at 20 normal cell to a cancer cell. 20 the rest of the data that fits, that it fits 21 So we know they have the 21 the definition of a nongenotoxic carcinogen 22 22 capability to induce tumors, or by its initial mechanisms to induce cancer. 23 cancer, all three of those, at least Q. Okay. And if talc is, in fact, 23 24 in animals if not in humans as well, 24 a nongenotoxic carcinogen, it would suggest 25 because two of them are known human. 25 that there is likely a threshold dose below

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1	which it does not have a carcinogenic effect,	1	what they've done, but is it possible
2	correct?	2	that they would do it? Any regulatory
3	MS. PARFITT: Objection.	3	agency, it's possible they could do
4	THE WITNESS: It is possible,	4	it, yes.
5	and that's the problem. In order to	5	QUESTIONS BY MS. BRANSCOME:
6	fully assess that, you would have to	6	Q. Do you have any information
7	have the data to prove it.	7	with respect to Health Canada's
8	But that's the assumption. You	8	decision-making, other than what you have
9	assume with nongenotoxic carcinogens	9	read on the face of the documents?
10	that you could identify a level where	10	A. That is all I have to look at
11	you wouldn't turn on that indirect	11	is what is provided on the website.
12	mechanism. So that yes, that is	12	Q. Okay. And so the statement
13	true.	13	that you think Health Canada was suggesting a
14	QUESTIONS BY MS. BRANSCOME:	14	dose threshold by their statement of
15	Q. And you have not been able to	15	discouraging routine use, you're basing that
16	identify, nor can you point to, scientific	16	entirely on what you read on the piece of
17	literature that identifies a threshold a	17	paper, correct?
18	threshold dose for talc with respect to its	18	MS. PARFITT: Objection. Form.
19	carcinogenic potential for ovarian cancer,	19	THE WITNESS: Well, that's what
20	correct?	20	they state. So, yes, I'm I am
21	A. Not a specific dose, but I	21	telling you what I see on their
22	think that's why I mentioned to you and	22	website. If that's what you're asking
23	I I think that's why Canada, when you look	23	me, yes, that is true.
24	at their document, they talk about	24	QUESTIONS BY MS. BRANSCOME:
25	discouraging routine use generally. So it's	25	Q. Okay. Can you point me
	Page 283		Page 285
1	the issue of what single use of a body	1	well, do you discuss have you looked at,
2	powder or an occasional use is a different	2	as part of your opinion specifically in the
3	risk assessment than routine use.	3	MDL, the studies exploring a potential link
4	So if you want to talk about	4	between asbestos and ovarian cancer? Just
5	thresholds that way, that's very imprecise,	5	asbestos.
6	but you could do that. You can talk about	6	A. Some of the studies, yes, but I
7	whether or not there I do believe there's	7	have not I have not done a separate risk
8	a different risk profile for one or two uses	8	1
9		_	assessment just for asbestos by itself,
9	of talc body powder versus a risk profile of	9	because I have not assumed that there is
10	somebody who uses it routinely, because I	10	because I have not assumed that there is asbestos-only exposure.
	somebody who uses it routinely, because I think that fits that threshold definition.	10 11	because I have not assumed that there is asbestos-only exposure. Does that make sense?
10	somebody who uses it routinely, because I think that fits that threshold definition. It's the idea that you have limited	10 11 12	because I have not assumed that there is asbestos-only exposure. Does that make sense? But I do cite for example, I
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Page 286 Page 288 1 Uh-huh. 1 not classified any of the heavy metals that 2 For example, have you rendered 2 you've identified in your MDL report as 3 an opinion about what dose of asbestos 3 carcinogenic to the ovary? exposure would be necessary to cause ovarian 4 A. So the answer is I'd have to 4 5 5 cancer in an individual? look. I don't recall that, but I'd have to 6 6 A. No, I have not formed that look to confirm. 7 7 opinion at this time. Q. Okay. 8 Q. Okay. Do you have an opinion 8 That's the answer I believe I 9 about the background level of asbestos to 9 gave a few minutes ago, yes. 10 which individuals are exposed with no 10 So if I look at the IARC increased risk of any type of cancer? 11 11 website, then I can confirm whether or not 12 A. No, I do not have an opinion. 12 they have identified any of those as 13 I do believe others do, but I do not. 13 carcinogenic to the ovary? Q. Okay. You may have been asked 14 14 A. Not so much the web -- well, 15 some of these questions before, but I will 15 the website or the actual documents. I think 16 keep them brief. 16 I would actually point you to the actual 17 Have you ever published any 17 monograph -articles that state that talc causes ovarian 18 18 Q. To the monograph. 19 cancer? 19 A. -- because there may be 20 20 evidence in there of ovarian cancer as being A. No, I have not. 21 Have you ever publicly 21 seen in studies. And I'd have to go look. 22 expressed the opinion that talc increases the 22 Okay. That was not part of your consideration here, correct? 23 risk of ovarian cancer outside of literature? 23 24 A. No. My work has been in the --24 A. So ovarian cancer is part of my consideration, but I didn't -- in this part 25 in the courtroom. 25 Page 289 Page 287 1 MS. BRANSCOME: I think we can 1 of my evaluation I'm trying to -- trying to 2 take a break. 2 describe these metals. And this is really 3 VIDEOGRAPHER: We are going off 3 about mechanism of biologic plausibility and the record at 2:57 p.m. 4 the fact that these two things can go 4 5 (Off the record at 2:57 p.m.) 5 together, and then the concept of additivity VIDEOGRAPHER: We are back on 6 is they're on hazard. The idea if you have a 6 7 cancer hazard generally and you have similar 7 the record at 3:13 p.m. 8 8 MS. BRANSCOME: Dr. Plunkett, I mode of action, regardless of the tissue, you 9 9 have no more questions for you on would be expected to have a potential 10 behalf of Johnson & Johnson, subject 10 additive effect when you do a risk to your counsel doing a direct of any 11 11 assessment. 12 12 kind. So that's my use of that data, 13 which is why I didn't do a separate ovarian 13 THE WITNESS: Sure. Thank you. **EXAMINATION** cancer assessment for each of the each 14 14 **QUESTIONS BY MS. BOCKUS:** 15 15 constituents but just on powder. 16 O. Good afternoon, Dr. Plunkett. 16 Q. And you discuss that topic on 17 You and I have met before. My name is Jane 17 page 47, paragraph 68, of your report, 18 Bockus, and as you know, I represent Imerys 18 correct, the -- whether there's an additive 19 19 in this case. effect? 20 A. Yes. 20 And you cite to Casarett and 21 Correct? 21 Doull. I don't know if I'm pronouncing those 22 I want to go back to just touch 22 names correctly. 23 briefly on a couple of issues that have A. I'm sorry, on what page? 23 24 already been addressed. 24 I'm on page 47, paragraph 68. 25 Would you agree that IARC has 25 Okay. Sorry. I should know

73 (Pages 286 to 289)

	Page 290		Page 292
1	where it is, but	1	a genetically susceptible mouse study
2	Okay. I'm there, yes. Okay.	2	to hurry the process along to look at,
3	Yes, I do cite to a chapter in	3	but you might not be able to do it
4	Casarett and Doull, yes.	4	through perineal exposure. You might
5	Q. Okay. And Casarett and Doull	5	have to do it through another route
6	is a resource that you cite to for a couple	6	such as either inhalation or maybe
7	of different toxicological principles that	7	even you could you could look at it
8	you discuss in your in your report,	8	through intraperitoneal injections,
9	correct?	9	
10		10	for example.
	A. Yes, because it's one of the	1	QUESTIONS BY MS. BOCKUS:
11	most well-recognized textbooks that is used	11	Q. Well, and what the textbook
12	across different either universities or	12	talks about is the fact that you need to
13	schools or even in regulatory agencies.	13	study it to find out whether the effects are
14	I would also say I cite EPA	14	additive, whether the effects are something
15	2000 there. I'm not citing just Casarett,	15	that multiply the risk, you know, so that the
16	but I am citing Casarett as well as an EPA	16	two together are greater than either one
17	guidance document.	17	alone, or do the effects offset each other
18	Q. In Casarett and Doull, do they	18	and reduce the risk, correct?
19	actually discuss talcum powder in Chapter 2,	19	A. That is discussed there
20	or is it more just the concept of the	20	MS. PARFITT: Objection.
21	potential of the effects when you have two	21	THE WITNESS: which is why
22	different chemicals that you're exposed to at	22	I've cited the EPA document. Because
23	once or three or four?	23	the EPA document addresses the issue
24	A. It's the latter. It's the	24	of mixtures, and this is the issue of
25	because you'll notice the title is	25	mode of action. If you have chemicals
	occurse you in motice the title is	25	mode of action. If you have chemicals
		25	
	Page 291	25	Page 293
1	Page 291 "Principles of Toxicology," so it's the	1	Page 293 that you're looking at on the issue of
1 2	Page 291 "Principles of Toxicology," so it's the general chapter teaching principles for risk	1 2	Page 293 that you're looking at on the issue of additivity or no effect, you will
1	Page 291 "Principles of Toxicology," so it's the	1	Page 293 that you're looking at on the issue of
1 2	Page 291 "Principles of Toxicology," so it's the general chapter teaching principles for risk	1 2	Page 293 that you're looking at on the issue of additivity or no effect, you will
1 2 3	Page 291 "Principles of Toxicology," so it's the general chapter teaching principles for risk assessment and toxicology as used in risk	1 2 3	Page 293 that you're looking at on the issue of additivity or no effect, you will you look at that issue of how they're
1 2 3 4	Page 291 "Principles of Toxicology," so it's the general chapter teaching principles for risk assessment and toxicology as used in risk assessment. Q. And whether there is an	1 2 3 4	Page 293 that you're looking at on the issue of additivity or no effect, you will you look at that issue of how they're affecting the tissue and underlying mechanism.
1 2 3 4 5	Page 291 "Principles of Toxicology," so it's the general chapter teaching principles for risk assessment and toxicology as used in risk assessment. Q. And whether there is an additive effect of, say, talc and nickel,	1 2 3 4 5	Page 293 that you're looking at on the issue of additivity or no effect, you will you look at that issue of how they're affecting the tissue and underlying
1 2 3 4 5 6	"Principles of Toxicology," so it's the general chapter teaching principles for risk assessment and toxicology as used in risk assessment. Q. And whether there is an additive effect of, say, talc and nickel, that's something that an experiment could be	1 2 3 4 5 6	that you're looking at on the issue of additivity or no effect, you will you look at that issue of how they're affecting the tissue and underlying mechanism. But the only way to look at the magnitude absolutely of how the risk
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Page 294 Page 296 1 is the fundamental principle of toxicology 1 A. That is true with the exception 2 that underpins the effects that chemicals can 2 of Parmley and Woodruff, which addresses this 3 have on living organisms? 3 issue of --A. When you're talking general 4 MS. PARFITT: Objection. 4 5 5 toxicology, yes, I think it's talked about in THE WITNESS: Talks about the 6 the textbook. 6 issue of exposure from the outside to 7 7 Q. And you agree that it is the the inside. 8 dose of the chemical and the pattern of 8 But the data that is collected 9 exposure that determines whether a chemical 9 with the different studies they have produces an adverse effect on an organism, 10 deposited at some point -- at some 10 not simply the presence of the chemical? 11 position within the vagina, that is 11 A. For a typical dose-response 12 12 true. 13 relationship for non -- for nongenotoxic 13 **OUESTIONS BY MS. BOCKUS:** events, absolutely, I would agree that is 14 14 Q. And that is not how talc is 15 probably true. And I don't mean nongeno --15 deposited in women who use it regularly in 16 noncancer events. 16 their daily routine, correct? 17 In the issue of cancer biology, 17 MS. PARFITT: Objection. some of those issues don't hold all the time. 18 Misstates the evidence. 18 19 In other words, there are certain chemicals 19 THE WITNESS: So I would say 20 and certain ways of looking at cancer risk 20 that depends on what women are doing. 21 assessment where you can't assume where the 21 Perineal application, for example, 22 threshold is or identify what a safe dose 22 application on the underwear, can lead would be. But certainly I agree on the issue to contact of the vaginal opening 23 23 24 of noncancer risk assessment generally, or 24 depending on the woman. 25 general end points of toxicity, that is true. 25 For example, a woman who has Page 295 Page 297 1 Q. And again, do you agree that in 1 a -- had many children has a tract general toxicology the effects that might be 2 2 that is stretched. There, indeed, you 3 reported at high doses will not occur at 3 can have more direct contact than you lower doses if the concentration at the site 4 can with a very tight -- so I would 4 5 5 of action falls below the threshold for say it depends on the woman and it 6 depends on the situation. 6 toxicity? 7 7 A. Yes, that could -- that could But I do think it's generally 8 be possible, yes. 8 accepted, based on my review of the 9 Q. And do you agree that 9 literature, that there is the 10 evidence-based toxicology and epidemiology 10 opportunity for exposure internally 11 dictates that the dose of the chemical is the 11 from perineal application. 12 QUESTIONS BY MS. BOCKUS: 12 critical factor when examining the risk posed by a chemical, not just its presence even in 13 13 Q. And if I understand what you the human body? 14 testified to earlier today and yesterday, you 14 15 A. I would say that's generally 15 don't have any data that would advise on --16 true, yes, which is why I have attempted to 16 out of the talc that is deposited in the 17 look at the dose-response relationship as 17 underwear, what percentage of it makes it 18 well as the prevalence of the contact. 18 into the reproductive tract? 19 Q. And with regard to the human 19 A. That's the data that's missing, studies that you cite, would you agree that 20 20 that is true. And unfortunately, no one has none of the studies that you cite in your 21 21 done a study. It would be -- if there was a report that have to do with migration of 22 22 way to do that, it would be interesting to do particles within the genital tract of the that. I just don't see how you design that 23 23 24 female involve applications to the perineum 24 study, especially knowing the hazard of talc 25 or outside of the genital tract? 25 at this point. I think that would be a

Page 300 Page 298 1 difficult study to get approval for. 1 migration occurs every day, once a week, once 2 Q. And do you have an opinion as 2 a month? 3 to whether it is even correct that each day 3 MS. PARFITT: Objection. Form. that a woman uses talc in her underwear, that 4 THE WITNESS: I haven't 4 5 5 some of the talc makes its way to the ovary? formulated my point -- my opinion quite that way; however, I do believe MS. PARFITT: Objection. Form. б 6 7 that it is something that is going to 7 THE WITNESS: Have I -- can I 8 quantify that? 8 happen routinely with exposure. I do 9 No, I haven't quantified it. I 9 believe that migration is something think I got asked that earlier. I 10 that is going on routinely with 10 can't quantify the amount that gets 11 application. 11 there. Or, I'm sorry, I may have 12 So with applications, I do 12 13 misheard the start of your question. 13 believe that that is, but I can't tell 14 I apologize. 14 you that this amount has migrated on 15 QUESTIONS BY MS. BOCKUS: 15 this particular day with this 16 Q. Yeah, I'm really asking: Do 16 particular application, no. That --17 you have an opinion as to whether it happens 17 the data that we have collected is not every single time a woman applies talc to her 18 there to allow us to do that. 18 19 perineal area? Does some of that talc make 19 QUESTIONS BY MS. BOCKUS: 20 20 it to her ovary? Q. How do you define the word "routinely" as you're using it in that 21 MR. MEADOWS: Objection. 21 2.2 MS. PARFITT: Objection. 22 answer? 23 THE WITNESS: I don't think I 23 A. So that would be the idea of 24 24 repeated exposures, you know, within a week, stated it quite that way, but 25 25 within a month, within a year. So not -certainly I think the opportunity is Page 299 Page 301 1 there with every application. And of 1 routine to me would not be -- would not be 2 course it would depend upon the amount 2 applying it once a month one month, waiting of time that the contact may be in 3 3 six months, doing it again, and then not 4 place. But the opportunity is there. 4 doing it until the next year. 5 5 So, for example, if you applied Again, it's the idea -- some 6 б it to your underwear and 30 minutes people may -- routine may be during the hot 7 7 season of the year, they're routinely getting later you go to the bathroom, it's 8 very possible that you will have wiped 8 daily exposures when it's warm, and during 9 9 away, and so that that application may the cold weather not applying. But then the 10 have taken an opportunity away. But I 10 next year doing -- that's a routine for them do believe that the opportunity is 11 and their habits based on their pattern of 11 12 12 there based on the literature I have exposure. 13 13 Again, we know that talc, when seen. 14 it -- when it migrates and gets into the 14 And so I haven't formed the 15 15 body, we have data to show that it is -- it opinion, though, that it's absolutely 16 every time. My opinion, I think, is 16 is able to persist in the body. The fact 17 based on the fact that I believe that 17 that you may have not been exposed for three 18 there is data to indicate that 18 months because it was cold doesn't mean that 19 19 you -- that that changes the fact that you're exposure occurs, and that with 20 20 still at risk with additional exposures the routine, continual habit, sort of a 21 habit exposure, that indeed that there 21 next -- the next time that that habit 22 was some migration that occurs. 22 becomes -- comes into place. 23 23 QUESTIONS BY MS. BOCKUS: So I think there's multiple 24 Q. And is it fair to say that you 24 exposure patterns that are possible, but when 25 don't have an opinion as to whether that 25 I use routine, it's something that people are

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Page 302 Page 304 opinion on a set number, no. I can't --1 doing throughout their -- a period of their 1 2 life. And so it would be something that 2 can't point you a specific number. 3 happens either on a weekly basis for a good 3 I'm not doing case-specific, so part of the year. I haven't defined it with 4 I've not looked at any of those pieces of 4 a particular number, though, no. 5 information for any given plaintiff. 5 6 6 O. And my question had to do with And I'm just trying to get the 7 7 out of the number of times a given woman -threshold. 8 or an average woman uses talc, what 8 A. Uh-huh. 9 percentage of the time does talc make its way 9 As I understand it, that is Q. 10 into her reproductive tract? 10 part of a toxicological evaluation, is the A. So I don't think that threshold below which there's not an issue. 11 11 12 anybody -- anybody can point to a piece of 12 So I think you've said you 13 data that tells you that, but, again, it's 13 don't know if it's less than a year, but you 14 based upon the anatomy, I would expect there 14 think it's more likely than not that it's 15 to be the potential each time it's applied. 15 greater than one month. 16 And on your question on 16 MR. MEADOWS: Objection. 17 17 routine, when I'm talking routine, I'm **QUESTIONS BY MS. BOCKUS:** looking at not just frequency but also 18 18 Q. Is that fair? 19 duration. So when I'm talking about dose, 19 A. No, that's not exactly what I'm 20 it's the fact that they do it on a repeated 20 saying. I'm saying we don't know the 21 basis for a number of -- a period of years as 21 threshold. So as a result, I'm not of the 22 well. 2.2 opinion that it absolutely can't -- it only 23 23 has to be this long. That's what the data shows in 24 the human studies. It's not something, 24 What I'm saying to you is per 25 again, that may have been done routinely for 25 general principles of toxicology and based on Page 303 Page 305 1 one year, but it does appear to be something the human data that we have, it indicates 2 that's done more -- longer term than that. 2 that it's more frequent than just one month, 3 But we can't give a number. We 3 but I can't tell you that it's absolutely not 4 have no threshold. We don't know exactly 4 possible. 5 what that minimum number is. 5 That's where -- I do think when б 6 Q. Do you think that the minimum you're talking about those kinds of patterns, 7 7 that's a case-specific issue for individuals, number is greater than a year? 8 because I think that would have to be 8 MS. PARFITT: Objection. Form. 9 THE WITNESS: I haven't formed 9 considered for each individual. But 10 that opinion, no. 10 certainly as a toxicologist, I'm using the 11 QUESTIONS BY MS. BOCKUS: 11 words "routine," "repeated," "longer 12 12 duration," "chronic exposure." And when I Q. Do you think it's greater than 13 a month? 13 defined "chronic" earlier, I talked about 14 MR. MEADOWS: Objection. 14 years of exposure versus just one month. 15 THE WITNESS: Greater than a 15 That would be consistent with 16 month? 16 what I have said, yes, but I'm not -- I -- I 17 QUESTIONS BY MS. BOCKUS: 17 certainly don't want to rule out that there 18 18 couldn't be somebody out there that could Q. Yes. 19 19 show something different, because it may very A. One month in their life? 20 well be that there are people that you can 20 One month in their life, where 21 21 they're using it every day for a month. identify with the presence of talc in their 22 A. So I haven't formed that ovaries and all of their other case-specific 22 opinion at this point in time, but I'd say 23 things that could -- could make that pattern 23 24 it's more likely to occur when you do it more 24 a -- make someone be able to draw a 25 than a month. But I haven't formed an 25 case-specific, reliable conclusion.

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Page 306 Page 308 **OUESTIONS BY MS. BOCKUS:** 1 But that's not my role. I 1 2 don't do case-specific. 2 Q. Okay. An ingredient supplier. 3 Q. And I am simply trying to get 3 And you agree that Imerys does 4 the parameters of your opinions with regard not sell any products to the general public, 4 5 5 to the amount of talc use one would need to correct? 6 MR. MEADOWS: Objection. 6 have before you would feel comfortable --7 THE WITNESS: I don't know 7 well, that in your opinion would be 8 8 that's definitely true, but I'm not sufficient to create a toxic environment. 9 MR. MEADOWS: Objection. 9 aware that they do. 10 QUESTIONS BY MS. BOCKUS: 10 THE WITNESS: Well, that's a 11 11 different question. So toxic Q. And what Imerys supplies to 12 12 environment could be with a much Johnson & Johnson is not a finished cosmetic 13 13 shorter time exposure, okay? that is ready to be sold on the market. 14 QUESTIONS BY MS. BOCKUS: 14 correct? 15 15 Q. Right. MR. MEADOWS: Objection. 16 16 MS. PARFITT: Objection. A. So but if you're talking 17 about -- the opinion that I have formed has 17 THE WITNESS: I don't know that 18 to do with an increased risk of ovarian 18 I can answer that except in the 19 cancer. So with that opinion, that's the 19 context of Johnson & Johnson's baby 20 description, I believe, I was giving this 20 powder, SHOWER TO SHOWER® and Shimmer, 21 morning. It's the idea that the data that 21 it's my understanding that Johnson & 2.2 I've seen indicates that my opinion that 22 Johnson mixes -- has some fragrance 23 perineal use of talc body powder products 23 added to the talc. 24 increases your risk for ovarian cancer above 24 I don't believe Imerys does 25 that background level that you know exists. 25 that, but I don't know for sure. Page 307 Page 309 1 That opinion is based on data 1 So based on what I know -- I'm 2 that is -- is -- the supporting data would 2 telling you what I know, and I would 3 indicate that it has to be a habit, routine, 3 call them, again, an ingredient 4 4 a chronic exposure. And so as a supplier, and I would call Johnson & 5 5 toxicologist, I've tried to put that in Johnson a cosmetic manufacturer. 6 6 context. Does that answer the question? 7 I don't know what else to tell 7 QUESTIONS BY MS. BOCKUS: 8 8 you. That's the opinions I have formed to Q. It does. 9 date. 9 Would you agree that the 10 Q. A chronic -- a habit, routine, 10 minerals that you have identified in your a chronic exposure for years? 11 11 report, that the documents that you have 12 A. Well, chronic --12 seen, would classify their -- to the extent 13 MR. MEADOWS: Objection. 13 that they are ever in the powder, that 14 THE WITNESS: -- is defined as 14 they're trace ingredients? 15 15 years, typically, by a toxicologist, MS. PARFITT: Objection. 16 and so that's what I -- that's what I 16 MR. MEADOWS: Objection. 17 told you. 17 THE WITNESS: So which QUESTIONS BY MS. BOCKUS: 18 18 ingredients are you referring to? So some of the metals, no, are 19 19 Q. Shifting to your regulatory 20 opinions, you would agree that Imerys is a 20 not trace ingredients. 21 raw material supplier to J&J; is that 21 Are you talking about the --22 22 are you talking about the -- like the 23 MR. MEADOWS: Objection. 23 presence of tremolite or the presence 24 THE WITNESS: I would call them 24 of chrysotile --25 an ingredient supplier, yes. 25

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Page 310 Page 312 1 QUESTIONS BY MS. BOCKUS: 1 **QUESTIONS BY MS. BOCKUS:** 2 Q. No. No, I'm sorry. I'm 2 Q. Have you seen any studies where 3 talking about the three metals that you 3 women's blood has reflected the presence of identify in your report. Those are trace 4 4 nickel or cobalt or chromium? elements that are -- that are sometimes 5 5 MR. MEADOWS: Objection. 6 6 detected in the studies of the -- of the **OUESTIONS BY MS. BOCKUS:** 7 7 talc Q. Who are parts of these 8 MR. MEADOWS: Objection. 8 studies -- these ovarian cancer studies? 9 THE WITNESS: It's not how I 9 MR. MEADOWS: Objection. 10 would say it. I would say they're 10 THE WITNESS: The heavy metal components that are 11 11 epidemiological literature you're 12 naturally occurring within the product 12 asking me? 13 that are sometimes -- sometimes 13 **OUESTIONS BY MS. BOCKUS:** 14 detectable at levels that are reported 14 O. Yes, ma'am. 15 as trace based on the detection limit 15 A. It's possible in the Nurses' 16 within the analysis, but at other 16 Health Study that we can go to that, because 17 times they're not listed as trace. I know they do collect some heavy metal 17 They're actually listed with a 18 18 levels. I've done that for other clients on 19 specific amount. 19 other issues. So that's what -- how I would 20 20 Most of the others, I doubt 21 define what I call trace. Usually 21 that we have heavy metal levels in blood. 2.2 that's how it will be reported in the 2.2 But certainly there are levels of heavy metal 23 lab, trace, which means below the in blood, especially things like lead, for 23 24 limit of quantification, but it's 24 example, that we have very limited capacity 25 there. You're detecting it. 25 to eliminate. Page 311 Page 313 1 I would agree that -- that 1 So whether or not you carry 2 there are other descriptions of heavy 2 around a significant body burden of a heavy 3 metals in the heavy metal literature 3 metal in your blood is somewhat driven by the that talk about trace amounts being 4 exposure pattern you get. It's something 4 5 5 found in -- naturally occurring in that's commonly -- or can you excrete it 6 quickly or not. So... 6 food, for example, and I agree that 7 7 that does occur. But in the case of Q. And are you familiar with any 8 8 studies that have suggested that the use of this product, we actually have 9 9 often -- we actually have a -- a limit body powders leads to a heavy burden of 10 that is set for acceptability in the 10 nickel, chromium or cobalt in the blood? 11 A. So I have not seen such 11 specification. 12 And so I would think it's more 12 analysis done, no, I have not. 13 Q. In paragraph 67 of your report, 13 proper to call it a level of the heavy 14 which is on page 46 -- I'm sorry, on -- oh, 14 metal that is allowable by the purity I'm sorry. Paragraph 64, I apologize. specifications set by the product. 15 15 16 And sometimes those levels may be 16 A. No. No, that's fine. 17 above, and most of the times those 17 Q. It's on page 44. levels are below, which is why it's 18 You cite to two abstracts --18 cleared. Because I've seen some 19 A. Yes. 19 Q. -- one by Fletcher and one by 20 20 analyses where different products may 21 have been, I guess, turned away or 21 Fletcher and Saed. 22 considered not acceptable based on the 22 Do you consider these abstracts analysis of certain types of minerals 23 2.3 to be reliable sources of data? 24 or metals. 24 A. They're not as reliable at all 25 25 as a peer-reviewed article. So there's a

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Page 314 Page 316 difference in the weight you give an 1 1 A. I attempted to do that. I 2 abstract, absolutely. 2 can't tell that you there isn't something in 3 However, knowing the papers 3 here I've missed. But, yes, I read this 4 report six or seven times before I finalized that Dr. Saed has actually published in the 4 5 it, trying to make sure that the language I 5 peer-reviewed literature, I have -- I have б was using was an accurate reflection of the 6 mentioned them in here because I do believe 7 7 opinion I'm expressing. that they are -- they are pieces of 8 information that are highly relevant to some 8 But it's possible, if you want 9 of the issues raised in other cellular 9 to point to something that you want to ask me studies, and so that's why they're here. But 10 about, I can tell you whether or not that was 10 certainly I do not give them the same weight 11 something that I would change. 11 Q. So on page 77, paragraph 118 in 12 as in my assessment of overall risk. 12 the middle of it, you say, "Based on the 13 And I would say that I had the 13 knowledge available by the 1950s, talc body 14 same opinions on risk before I had these 14 15 studies. Because in my original reports, 15 powders manufactured and sold by Imerys and 16 obviously, I have gone further than risk and 16 Johnson & Johnson." 17 talked about cause, and I didn't have the 17 And that's the question that I Fletcher studies. 18 18 have for you. 19 The Fletcher studies are more 19 A. I see what you're saying. 20 20 Q. Was Imerys selling anything to on the issue of biologic plausibility and 21 mechanism versus being important 21 Johnson & Johnson in the 1950s? 22 underpinnings, for example, for a hazard 22 MR. MEADOWS: Objection. assessment. THE WITNESS: I'm thinking. 23 23 24 Q. Is there any way that someone 24 It's possible they did not. That may reading your report could tell that you 25 25 be true. Page 315 Page 317 1 attribute less weight to the abstracts by 1 **QUESTIONS BY MS. BOCKUS:** 2 Saed and Fletcher just by reading your 2 Q. Well, and actually --3 report? 3 You know what? When I wrote 4 MR. MEADOWS: Objection. 4 this sentence, I assumed that they did, but 5 5 THE WITNESS: I don't know if if that is not true, then certainly this 6 they could or not. Hopefully they 6 sentence should be just Johnson & Johnson. 7 would based upon where they appear in Q. Well, earlier in your report, 7 8 the report. They're not cited a lot 8 in a footnote you indicate that Imerys began 9 9 of other places, but they certainly supplying talc to Johnson & Johnson in 1989 10 are cited. 10 or the late 1980s. So that's why I'm here today, 11 Do you remember making that 11 though. You're asking me these 12 12 notation? questions; I'm telling you. That's 13 13 A. So let me look. So if that's how I look at these studies. That's 14 an inconsistency, then that should change. 14 15 15 all I can say. Let me look. Q. And that's all I want to know, 16 I haven't -- I haven't, 16 17 certainly, as I've told you, given 17 if it's an inconsistency, should it change. 18 things numerical weight throughout my 18 A. If it is an inconsistency --19 19 certainly if Imerys was not selling talc to report. Johnson & Johnson in 19 -- the 1950s, then --20 QUESTIONS BY MS. BOCKUS: 20 then certainly Johnson & Johnson's products 21 Q. Looking at paragraph 118... 21 would not -- would not be affected by Imerys' 22 Well, when you were preparing 22 your report, were you careful with the 23 23 activity. 24 language that you used in it to be precise 24 However, if Imerys is selling 25 and accurate? 25 talc to anyone that makes a consumer product

Page 318 Page 320 1 in the 1950s, then -- or a precursor company 1 complete assessment the way I did, then I 2 to Imerys is making talc that's selling for 2 would agree that other people could come to a 3 body powder to somebody other than Johnson & 3 different conclusion, absolutely. 4 Johnson, then that opinion would still hold. 4 So I think it depends what you 5 So -- but I certainly agree, I 5 mean by "reasonable scientist." But I would 6 think I -- you're right, I think I have a 6 agree that individuals can look at the same 7 statement about the link between the two in 7 body of data and, based on their judgment and 8 '89. So in that case, then certainly the --8 experience, based on looking at that same 9 the link here would be related to Johnson & 9 body of data, could come to a different 10 Johnson's products. 10 conclusion, yes. That's true. 11 Q. Okay. Yeah. Q. You've been involved in this 11 12 A. Whether or not -- if they 12 talc litigation for at least a couple of 13 weren't sourced from Imerys, then that's a 13 years, right? 14 separate duty on a product, not this product. 14 A. Yes. 15 Q. If you look on the bottom of 15 Q. And you know that various 16 page 7, I think you'll see the footnote I was 16 defendants have offered experts who disagree with your conclusions, right? 17 referencing. 17 18 18 A. Some of my conclusions, yes. I And with regard to your last 19 answer, you don't have any information as to don't know that there is somebody that's in 19 20 whether Imerys existed and, if it did, 20 the litigation that does exactly what I do 21 what -- who its customers were in 1950s, 21 across all the opinions I've expressed, but, 22 correct? 2.2 yes, certain parts of my opinions there are 23 23 other experts I'm aware of, yes. A. I don't believe I do, no. Q. Well, they -- you're aware that 24 MS. BOCKUS: I think that's all 24 there are defense experts who disagree with 25 that I have. Thank you. 25 Page 319 Page 321 1 MR. LOCKE: I've got a few 1 your opinion that talc increases the risk of 2 questions. 2 ovarian cancer; is that correct? 3 **EXAMINATION** 3 A. Yes, I -- I am aware of that 4 **OUESTIONS BY MR. LOCKE:** 4 fact. 5 5 Q. Doctor, my name's Tom Locke. I Q. And in your review of the 6 represent the Personal Care Products Council. 6 records that go back or the scientific 7 7 We met a couple of times before, I think. materials that go back 35 years or more, 8 8 A. I apologize, I don't recall you've seen that there's disagreement 9 your name at least. The face looked 9 regarding that issue; is that correct? 10 familiar, though. I apologize. 10 A. So what documents are you 11 Q. I try to maintain a low 11 referring to? Are you asking me about a 12 12 specific -- just the published medical profile. 13 13 literature? Are you asking about documents I have relatively few 14 questions. I wanted to ask you overall about 14 like internal company documents, reviews by 15 your opinion. 15 others? What are you asking me about? O. Well, let's focus on the 16 Would you agree that reasonable 16 published medical literature. 17 scientists can disagree with your opinion 17 18 that talc increases the risk of ovarian 18 There are scientists who have 19 19 disagreed with your opinion; is that correct? cancer? 20 A. I'd say I wouldn't say it quite 20 MS. PARFITT: Objection. that way. I'd say that I agree that 21 21 THE WITNESS: I'm not aware of 22 scientists can disagree on conclusions they 22 a paper in the published medical 23 draw, depending on the -- depending on the 23 literature that has done the exact way that they have assessed. 24 24 assessment I have done. 25 So certainly based on a 25 So I am aware of the fact,

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Page 322 Page 324 1 however, that there are individual 1 what I've been doing in the litigation. 2 papers by scientists that, for 2 Q. Okay. As to that second 3 example, have concluded that there is 3 bucket, the US regulatory requirements for 4 no association between exposure to marketing cosmetic ingredients and products, 4 5 5 talc perineally and ovarian cancer, that's not relevant to the scientific 6 6 ves. Individual papers, I am aware of question whether talc may cause ovarian 7 that, but that's different than what I 7 cancer; am I right? 8 have done. 8 A. No. I disagree with that based 9 QUESTIONS BY MR. LOCKE: 9 on the fact that a company that markets a 10 Q. Let me just ask you about what 10 cosmetic product is required to do a safety you were requested to do on behalf of assessment. And if in that safety assessment 11 11 12 plaintiff's counsel. 12 issues relate to cancer or ovarian cancer and 13 Plaintiff's counsel asked you 13 the use of talc, then those two things are 14 to provide opinions related to the human 14 related. 15 health hazards posed by exposure to talcum 15 But I would agree that -- that 16 powder products and how those hazards relate 16 doing a risk assessment like I've done is a 17 to the regulatory requirements for marketing 17 separate issue from doing a safety assessment cosmetic ingredients and cosmetic products in 18 for a product, because there's actually even 18 19 the United States; is that correct? 19 a lesser standard for an issue of looking at 20 MR. MEADOWS: Objection. 20 a safety assessment for a product versus 21 THE WITNESS: I didn't write 21 actually forming the opinion that there is an 2.2 that, but that sounds like an accurate 2.2 increased risk of cancer with exposure to 23 23 reflection of what -- what we -- what talc. 24 I have done at least in parts of my 24 Q. Now, did IARC in 2006, did it 25 25 report, yes. look at the US regulatory process in Page 323 Page 325 1 **OUESTIONS BY MR. LOCKE:** 1 considering whether talc may cause ovarian 2 Q. Well, if you look at your 2 cancer? 3 report, I think you go to part where you were 3 MR. MEADOWS: Objection. asked to provide -- and I just pulled it from 4 THE WITNESS: I don't think I 4 5 5 what you said. understand what you mean. It's not a 6 6 US regulatory process, no, if that's A. So I did write it, I apologize. 7 7 It didn't sound like me. what you're asking me. 8 8 They have a -- they have a Q. It started with "to provide 9 opinions related to the human health hazards" 9 discussion of what the products are, 10 and so forth, so I just wanted to make sure 10 which is part of the way they're sold. 11 we're clear on that. 11 But I don't think they're discussing 12 A. Sure. 12 the duty of a company under the regulatory process, no, that's a 13 So does that sound right in 13 Q. 14 terms of what you were asked to do? 14 separate issue. 15 A. I said I -- certainly those are 15 QUESTIONS BY MR. LOCKE: 16 the kinds of things that I was definitely 16 Q. So their analysis of whether 17 asked to do. I was asked to do two basic --17 talc may cause ovarian cancer, that's 18 two basic things, which was having to do with 18 different than the analysis of whether a 19 toxicology and risk assessment, and then a 19 company may have a duty, whatever that duty 20 separate issue related to regulatory 20 may be? 21 concerns. 21 MR. MEADOWS: Objection. 22 22 THE WITNESS: It's a different So, yes, those are the two process, absolutely. IARC is a 23 basic, I guess, buckets of information and 23 24 documents that I reviewed and opinions I've 24 separate, independent body that does 25 expressed, and I think that's consistent with 25 an assessment looking at the issue of

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1	cancer hazard and looking at whether	1	this is a different assessment and
2	or not there is sufficient evidence to	2	different standard. It's a much lower
	3 categorize that hazard, whereas a duty		standard on cosmetics for what needs
4	of a company under the regulatory	3 4	to be done as far as warning.
5	situation is broader than just cancer	5	Now, when a company comes and
6	hazard; it's a whole different thing.	6	initiates a safety assessment on their
7	It's what you do internally before you	7	product, before they even think about
8	market a product. Totally different.	8	what am I going to warn, they should
9	And so certainly when I	9	be doing a comprehensive assessment of
10	that's why I have separate sections in	10	safety based on what's available
11	my report, and that's why I even	11	publicly, knowing what others have
12	have I've had discussions about the	12	reported and then what data they've
13	difference between the regulatory	13	collected.
14	standard for warning versus the	14	If they don't have data at all
15	assessment of risk that may be	15	on the safety of the product, then the
16	required in order to start to produce	16	product has to say that. We don't
17	a identify a association or an	17	know. We do not know if this product
18	increased risk or even if you did a	18	is safe. And that's one of the things
19	causation analysis. Totally different	19	that is allowed under FDA under FDA
20	type of exercise.	20	regulations as well.
21	QUESTIONS BY MR. LOCKE:	21	But essentially some some
22	Q. Do you first, in that exercise,	22	assessment must be done to understand
23	look at the scientific issue of whether talc	23	from the perspective of the company
24	may cause ovarian cancer?	24	that this product is safe for
25	A. Are you asking me in either of	25	consumers to use as under the
23	71. The you asking me in cliner of	23	consumers to use as under the
	Page 327		Page 329
			1436 327
1	these exercises?	1	directions of use.
2	Q. Well, let's say when you're	2	directions of use. So in the case of this, it
2 3	Q. Well, let's say when you're getting to you mentioned the duty to warn.		directions of use. So in the case of this, it would be a body powder being used on
2 3 4	Q. Well, let's say when you're getting to you mentioned the duty to warn. So if you're looking at the duty to warn, do	2 3 4	directions of use. So in the case of this, it would be a body powder being used on the body surface but also perineally
2 3 4 5	Q. Well, let's say when you're getting to you mentioned the duty to warn. So if you're looking at the duty to warn, do you first have to look at does talc cause	2 3 4 5	directions of use. So in the case of this, it would be a body powder being used on the body surface but also perineally because because that was an
2 3 4 5 6	Q. Well, let's say when you're getting to you mentioned the duty to warn. So if you're looking at the duty to warn, do you first have to look at does talc cause ovarian cancer?	2 3 4 5 6	directions of use. So in the case of this, it would be a body powder being used on the body surface but also perineally because because that was an exposure pattern that was understood.
2 3 4 5 6 7	Q. Well, let's say when you're getting to you mentioned the duty to warn. So if you're looking at the duty to warn, do you first have to look at does talc cause ovarian cancer? MR. MEADOWS: Objection.	2 3 4 5 6 7	directions of use. So in the case of this, it would be a body powder being used on the body surface but also perineally because because that was an exposure pattern that was understood. QUESTIONS BY MR. LOCKE:
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	Q. Well, let's say when you're getting to you mentioned the duty to warn. So if you're looking at the duty to warn, do you first have to look at does talc cause ovarian cancer? MR. MEADOWS: Objection. THE WITNESS: That's not the question you asked. No. I would argue, based on the regulations, if you look at the standard, the question is, is there evidence to indicate that there is a chance, there is a potential not that it does, but is there a potential for that type of hazard to be posed to consumers who use the product. It's a possibility versus being a I'm taking it beyond possibility when I'm doing my assessment for increased risk. And I talked about that this morning, and I can't remember her last name. The	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	directions of use. So in the case of this, it would be a body powder being used on the body surface but also perineally because because that was an exposure pattern that was understood. QUESTIONS BY MR. LOCKE: Q. Okay. You described two different buckets. They're independent assessments; is that correct? MR. MEADOWS: Objection. THE WITNESS: Initially that's where I started, and now I'm talking two different duties. There's a duty to warn, but there's first a duty to collect information before you market it. It's your premarket safety assessment. QUESTIONS BY MR. LOCKE: Q. Okay. I'm not actually talking about the manufacturer's duty. I wanted to just first address your scientific analysis. That's a separate question that

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Page 330 Page 332 1 ovarian cancer, correct? 1 also sort of -- that's a piece along the way 2 MR. MEADOWS: Objection. 2 to doing a causation analysis, but it's not 3 THE WITNESS: Yes, that's what 3 the same. Q. Your opinion regarding the 4 I described. And I thought you were 4 5 talking about duty of the company, and 5 FDA's responsibilities and functions, that's 6 so I apologize. I didn't mean to go 6 not related to your opinion that talc may 7 off on a tangent. 7 cause an increased risk in ovarian cancer; is 8 If you want to focus just on 8 that correct? 9 the risk assessment -- is that what 9 MR. MEADOWS: Objection. 10 you want to do? -- that's what I'm 10 THE WITNESS: I don't think 11 11 that's true the way you're asking that 12 QUESTIONS BY MR. LOCKE: 12 question, because I don't know how you 13 Q. No, I just want to understand, 13 divorce the fact that as a -- in a 14 those are two different things, though, 14 regulatory assessment, if I identify 15 15 cancer hazard, I have identified a 16 Those are two different --16 duty to warn. That's certainly A. 17 those are two different tasks that I 17 something that should be warned about 18 undertook, yes. I undertook a risk 18 when I understand that there's not 19 assessment task to form opinions based on 19 only the potential, but I believe 20 what I can say about risk, and then I 20 there's an increased risk. 21 separately -- and I had done this earlier on 21 But I would agree with you that 22 the issue of warnings, looking at what do we 2.2 in my report, I'm laying out for you 23 know about the product and whether or not -even different bodies of information 23 24 and when did we know it, and what should 24 that -- as I step through it. 25 consumers have been warned about based on the Does that make sense to you? 25 Page 331 Page 333 1 safety information that was available over 1 **QUESTIONS BY MR. LOCKE:** 2 time. 2 Q. Not really. 3 The risk assessment task, 3 A. I'm sorry. that's what you mean by your analysis that 4 Q. I'm talking about your 4 5 5 talc increases the risk of ovarian cancer? scientific analysis here, not your regulatory 6 6 A. That's correct. analysis. 7 7 You could have stopped at that, To do your scientific analysis, you looked at scientific materials, right? 8 but then you performed an additional task; is 8 9 that right? 9 A. Yes, but I do the same thing 10 A. Well, actually, no, because the 10 for my regulatory analysis. That's why I'm 11 first task I actually started with was the 11 confused. I -- to me they are connected. regulatory task. When I first started 12 But I would agree with you, I 12 getting involved in the litigation very --13 had an analysis. Let's just talk about that, 13 before I wrote my first report, one of the 14 my analysis on risk assessment and my 14 15 first things I was looking at was the issue 15 opinions that I've expressed. Those are laid 16 of the duty of the manufacturer to provide 16 out in a separate section of my report, 17 warnings. 17 absolutely. So we could talk about that if 18 And then after that, I expanded 18 you'd like. 19 that role to be an inclusion as well of a 19 Q. Well, I just want to 20 causation analysis. 20 understand, and I think I do now, that's a 21 And then now I'm not doing a 21 separate issue from your regulatory opinion? 22 22 A. It's not a separate issue. full causation analysis in this litigation, but I'm using essentially some of the same That's where I'm having trouble with your 23 23 24 information to provide you with a description 24 language. 25 of a -- a health risk assessment, which was 25 It's a separate task because,

Page 334 Page 336 1 for example, I may have only been asked, but 1 But I practice in both those areas in 2 I wasn't, to just describe whether or not, as 2 my consulting practice and in my 3 a human risk assessor and toxicologist, there 3 experience. 4 4 is a hazard or a risk posed by the product, QUESTIONS BY MR. LOCKE: 5 5 and I could stop there. Q. Let me ask you a few questions 6 6 But I was asked, based on -about your cosmetic ingredient review 7 7 based on my experience working in the area of statements, CIR. 8 regulatory toxicology but also on regulatory 8 We can agree to call it that, 9 issues for clients where I give advice, I was 9 right? 10 asked to look at how does that scientific 10 Yes, that's fine. 11 information impact what the company should be In parts of your report, you 11 Q. 12 12 cite the CIR as an authoritative source on doing. 13 And so that's -- that's why I'm 13 cosmetic ingredients; is that correct? 14 saying you can't divorce them, because the 14 A. So where are you looking at, 15 warning issue I'm talking about is intimately 15 the background information on the CIR? 16 tied into the human health risk assessment 16 Yes, they certainly are a source of information that FDA relies upon as 17 results. 17 18 far as assessments, yes, that's true. Q. So do you consider yourself 18 Q. Well, and on page -- or 19 primarily here as a warning expert? 19 20 MR. MEADOWS: Objection. 20 paragraph 35, page 23, you cite to the CIR 21 THE WITNESS: I consider that 21 on, for example, chemicals purportedly in 22 one of my roles, yes, absolutely. 2.2 cosmetics. You have a footnote there. 23 It depends upon how individual 23 So --A. 24 cases, individual attorneys, will --24 Q. I believe it's footnote 31. 25 will ask -- decide to use me. For 25 Yes, I have looked at -- looked Page 335 Page 337 1 example, I have been used in one trial 1 at the CIR as a source of information because 2 to only talk about the toxicology. 2 many of the chemicals, many of the 3 Other trials, I've talked about 3 ingredients within the fragrance of Johnson & 4 toxicology as well as regulatory 4 Johnson, the only available information may 5 5 issues. So I think it just depends on be found within the CIR that's publicly 6 6 available. the case. 7 In the MDL, I am prepared, 7 Q. And you rely on the report of 8 8 Dr. Cralley; is that correct? however, to come to talk at a trial on 9 the regulatory system that guides 9 MR. MEADOWS: Objection. MS. PARFITT: Objection. 10 cosmetics as well as provide opinions 10 that talk about what are the hazards 11 QUESTIONS BY MR. LOCKE: 11 12 of talc, what is the toxicology of 12 Q. You reference Appendix D to 13 your report. I believe if you stay on the 13 talc, what do -- how can you be 14 exposed to talc, that migration issue, 14 same page you'll see that, the same 15 and then my opinions about whether or 15 paragraph. 16 not I believe that there is an 16 I wouldn't say I rely on the 17 increased risk of ovarian cancer. 17 report of Dr. Cralley because I form my 18 So I would be -- be prepared to 18 opinions independent of Dr. Cralley, but 19 19 certainly his -- I believe if you go to his talk about both of those things. 20 20 reports, his report is supportive of my That's why I said I do think I'm a opinions in this area. 21 little different than some of the 21 22 other experts that you may encounter, 22 O. Did you read his report? 23 A. I have read it now, but I did 23 for example, in the defense side, 24 where someone may just do regulatory 24 not read it before I -- before I formed my 25 or somebody may just do toxicology. 25 opinions in this particular paragraph, yes.

Page 338 Page 340 1 Q. I'm a little confused because 1 is no other source available. 2 you're citing to his report. 2 Q. Okay. In your report you state 3 You read it or you didn't read 3 that the CIR process is administered it before you wrote this paragraph? 4 independent of the FDA. 4 A. I read it before I wrote the 5 5 But the FDA is on the CIR 6 6 paragraph. I didn't read it before I had steering committee; is that correct? formed the opinion. Do you understand what 7 7 A. That is correct. Q. You don't mention that in your 8 I'm saying? 8 9 I did my review of the irritant 9 report, although you mention others who were chemicals independently before I looked at 10 on the CIR steering committee, correct? 10 A. Yes, there's a paragraph where Dr. Cralley's report. So I had formed the 11 11 opinion that -- of the chemicals I had 12 I talk about others, yes. 12 13 searched for that this is what I identified. 13 Q. But you don't mention that the FDA is on the steering committee? 14 And that's what this is talking about, right? 14 15 I'm saying here that of the 15 A. I believe I -- I believe I've 16 more than 100 chemicals included, over 16 been asked that question before, and I said 17 70 percent are compounds linked with some 17 yes, but certainly in this report I don't level of irritant hazard. That was done on believe I state that, that is true. 18 18 my own. Q. CIR solicits input from the 19 19 20 20 public; is that correct? Then, if you go to look at 21 Dr. Cralley's report, I cite it here because 21 MS. PARFITT: Objection. 22 it's consistent. That is, his report 2.2 THE WITNESS: I would say they 23 provides support additionally for the 23 solicit input from industry, yes. 24 statement I'm making. 24 QUESTIONS BY MR. LOCKE: 25 So I'm not relying on his 25 Q. Well --Page 339 Page 341 1 conclusions to make my opinion, but it's 1 A. But they -- and they do have a 2 certainly -- I am citing it here as it being 2 public comment period, which is mainly input 3 a piece of evidence that is consistent with 3 from industry. 4 my opinions. 4 But I agree that they do -- and 5 5 Q. Sorry, I seem to have messed up if what you're referring to is a public my microphone. I'll try to hold it for a 6 comment period, yes, there is that for the 6 7 7 little bit then. documents. 8 8 Do you disagree with Q. You can go on the website and Dr. Cralley's report? 9 9 see what ingredients CIR is going to review, 10 A. I have not formed an opinion 10 right? 11 that I agree or disagree. He -- with his --11 Yes, you can. A. I believe he has information that is Have you done that? 12 12 Q. consistent with the opinion I'm expressing in 13 Yes, I've done it many times 13 A. the sentence, however. 14 14 before. 15 Q. And do you know that 15 Okay. And did you submit O. 16 Dr. Cralley repeatedly cites to the CIR as an 16 comments on talc in 2012? 17 authoritative source regarding cosmetic 17 A. No, I did not. 18 ingredients? 18 Okay. You could -- the public 19 A. I don't know that he uses that 19 can submit comments many times during the 20 exact language, but he does cite to it, yes, 20 process of an ingredient review; is that in his report. Certainly he does. 21 21 correct? 22 O. More than 20 times, right? 22 There are different --Α. That, I have not counted. I 23 different stages of the draft document. Is 23 24 can't tell you that. But he does, just like 24 that what you're asking me? Yes, that can be 25 I do, as a source of information when there 25 done.

	Page 342		Page 344
1	Q. Well, even before it's a draft,	1	submitted.
2	CIR is soliciting information about the	2	Q. And CIR meetings are open to
3	ingredient to include in the initial	3	the public, right?
4	materials provided to the expert panel; isn't	4	A. That is true, they are open to
5	that correct?	5	• • • • • •
6			the public, but in my experience it they
	A. Technically I believe that is	6	are not meetings that are heavily attended by
7	true, but I would disagree that that is	7	the public but indeed are tend to be
8	something that happens routinely. But I	8	meetings attended by industry stakeholders
9	would agree that I would say technically	9	within the ingredients that are being
10	you may be that is something that could	10	reviewed.
11	occur, yes, but that is not the situation,	11	Q. You know Mr. Steinberg here.
12	for example, in the case of talc.	12	He was a plaintiff's expert for a while?
13	Q. Why not?	13	A. I don't know him personally,
14	A. Based upon what I have seen	14	but I know his name and I know he was a
15	described as how the review was done, and	15	plaintiff's expert, yes.
16	that has to do with the testimony of	16	Q. You know he attended the talc
17	different or different documents that I've	17	meeting, right?
18	reviewed and the testimony of individuals	18	A. Yes, I believe he was working
19	related to this document.	19	with indus he works with industry, so I
20	Q. Well, Dr. Cramer could have	20	believe indeed he did attend that meeting.
21	submitted comments to the CIR regarding talc,	21	Q. You're not claiming he was
22	couldn't he?	22	working with any industry member regarding
23	MR. MEADOWS: Objection.	23	talc, are you?
24	MS. PARFITT: Objection.	24	A. That's not what I stated. I
25	THE WITNESS: You'd have to ask	25	know he's a consultant to the cosmetic
	Page 343		5 245
	rage 343		Page 345
1		1	
1 2	Dr. Cramer if he was aware that they	1 2	industry, so it doesn't surprise me. And I
2			industry, so it doesn't surprise me. And I believe he lives in the area, so it doesn't
2 3	Dr. Cramer if he was aware that they were reviewing it. I can't answer that for Dr. Cramer.	2	industry, so it doesn't surprise me. And I believe he lives in the area, so it doesn't surprise me that he attended.
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Page 346 Page 348 1 tale at that particular time. I have a lot 1 same level of review of any of these 2 of other clients and a lot of other issues 2 ingredients as can be provided -- as was 3 that go on on a routine basis, and I -- I 3 provided by the IARC. 4 4 And so, again, that's one of literally would not have time to follow every 5 5 assessment they do, considering that they do the comparisons I'm doing. I'm talking about б the difference in the time, the effort, the 6 thousands of chemicals. 7 7 Q. Did you know of the CIR prior difference in the independence of the 8 to your retention by plaintiff's counsel? 8 reviews. And so that -- when I'm talking 9 A. Yes. In fact, I -- one of the 9 about, those numbers, that's what I'm 10 10 journals that I receive, International focusing on. I'm focusing on the fact that 11 11 you have so many reviews in a very short Journal of Toxicology, maybe, publishes many 12 of their safety assessments. So I certainly 12 period of time, with a one-expert panel, it's 13 13 impossible for that level of analysis and am, yes. 14 I was aware -- when I was at 14 review to be anywhere near what IARC panels 15 Eviron, I was aware of the existence of CIR. 15 do, and also nowhere near the level of review 16 Q. Have you ever provided prior to 16 that I have done based on the number of 17 this litigation -- and by "this litigation" I 17 documents that I have analyzed and looked at. mean any aspect of the talc litigation -- an 18 So it's a different type of review. 18 expert opinion on cosmetics' ingredients? Q. Let me ask you a few questions 19 19 20 A. You're asking me in any other 20 because you have criticized the panel. 21 litigation on a cosmetic ingredient? 21 You would agree with that, 22 I'm thinking back to the cases 22 correct? I've worked on. Not as a -- not as a 23 23 Yes. Oh, absolutely. This 24 24 particular analysis I have. I have made some testifying expert. 25 25 general criticisms of the overall process, At Eviron, though, we worked on Page 347 Page 349 1 litigation involving cosmetic ingredients, 1 and then I made some specific criticisms of 2 thought I was not the testifying expert. 2 this particular review. 3 Q. In your report you talk about 3 Q. And one of your criticisms is the percentage of -- or the number of 4 that the CIR -- I think you said two CIR 4 5 5 ingredients that the CIR listed as unsafe. expert panelists had conflicts of interest; 6 6 Do you recall that? is that correct? 7 7 A. Yes. I mean, if you want me to A. Yes, that -- they did, that 8 verify the number, I need to go there. But, 8 were not -- that were not -- I believe not 9 9 yes. understood even by Dr. Andersen at that time. I think these are things brought up to him 10 Q. You don't mention that CIR has 10 11 put limitations on approximately 50 percent 11 that he was not aware of. of the ingredients that it has reviewed, do 12 12 Q. All right. Now, you read his 13 testimony in one of the trials in California, you? 13 14 14 A. I don't mention that, but they right? 15 do. They have -- they have -- when they have 15 Yes, that's the -- in fact, 16 a statement about safety, they will -- they 16 that's the source of the information where 17 will often talk about the limitations from 17 I'm citing to those names of those 18 the safe use based on either concentration or 18 individuals. I think I refer to that, his 19 19 even maybe route of exposure, that is true. trial testimony. 20 Q. Why don't you do that? Why 20 Q. And didn't he, though, say, didn't you include that in your report? 21 21 well, he didn't view it as a conflict of 22 A. No particular reason. I mean, 22 interest because the money wasn't going to 23 the point I'm trying to make is really the 23 them personally, it was going to their 24 workload that's going on here and the 24 organizations? 25 impossibility of the task of providing the 25 A. He did make that statement,

	Page 350		Page 352
1	yes.	1	from an industry or a company that has
2	Q. And you disagree with that	2	to do with the issue you're looking
3	statement?	3	at, yes, a conflict a conflict of
4	A. I don't I mean, his	4	interest absolutely needs to be
5	testimony is what it is.	5	described.
6	Are you asking me do I disagree	6	QUESTIONS BY MR. LOCKE:
7	that that's a conflict of interest?	7	Q. And that would well, let me
8	I disagree that you shouldn't	8	just ask you: You're not an ethicist, are
9	disclose that as a potential conflict in the	9	you?
10	documents that are produced, just like I do	10	A. No, I'm not trained as an
11	when I write an article and I disclose that	11	ethicist.
12	I've had funding. I don't say what the	12	Q. And you're not a lawyer, are
13	funding specifically paid for, but I've had	13	you?
14	funding or support from this industry	14	A. Well, no, but I have passed the
15	individual or that industry individual.	15	patent bar, but I'm not trained as a lawyer.
16	It's it's something that just is about	16	Q. That doesn't make you an
17	transparency.	17	ethicist, right?
18	Q. So when you write articles, you	18	A. No, it does not.
19	say that you've been paid a lot of money by	19	Q. Okay. Let's talk about one of
20	plaintiffs' lawyers?	20	the people you criticized, Dr. Wilma
21	MR. MEADOWS: Objection.	21	Bergfeld.
22	MS. PARFITT: Objection.	22	Did you know she was the first
23	THE WITNESS: Well, I haven't	23	woman who was the president to be the
24	written an article that overlaps with	24	president of the American Academy of
25	an issue that I've addressed in	25	Dermatology?
	Page 351		Page 353
			1430 555
1	plaintiffs' litigation, but I	1	A. No, I don't know her
2	certainly have given my conflict of	1 2	A. No, I don't know her personally, so, no, I did not know that.
		1	A. No, I don't know her personally, so, no, I did not know that. Q. Did you investigate her at all
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	Page 358		Page 360
1	causation analysis a wide variety of studies.	1	I'm sorry.
2	So I do think it's important.	2	Q. The FDA frequently seeks
3	Q. You're not a gynecological	3	information, scientific information, from
4	oncologist, are you?	4	cosmetic manufacturers; is that correct?
5	A. No, I'm not. But again, that	5	A. I don't understand what you
6	would have been an important expertise to	6	mean by "frequently seeks." They rely on
7	have on the panel when	7	cosmetic manufacturers to do their own safety
8	Q. And yet you formed your opinion	8	assessments.
9	with	9	Is that what you're referring
10	MR. MEADOWS: Hold on.	10	to?
11	MR. LOCKE: No. No. Go ahead.	11	Q. Well, they ask PCPC to comment
12	You can ask follow-up questions	12	on scientific issues, correct?
13	if you want.	13	A. Yes, I would agree that that
14	MR. MEADOWS: You're	14	interaction has happened, but that's not
15	interrupting her.	15	where the responsibility lies. But I agree,
16	MR. LOCKE: Well, I've got a	16	they have.
17	limited amount of time, and I've got	17	Q. I'm not asking about
18	to keep moving.	18	responsibility. I'm asking: Has the FDA
19	MR. MEADOWS: Well	19	asked cosmetic manufacturers for scientific
20	MR. LOCKE: They're very long	20	information?
21	answers to questions that I'm not	21	A. Yes, they have in this case. I
22	asking. So I you follow up if you	22	discuss some of that, yes.
23	would like with your questions, but I	23	Q. And they do that frequently,
24	got to keep moving.	24	right? Not just in this case, but generally?
25	MR. MEADOWS: Well, I'm sorry,	25	A. I can't answer that for all
	250		2.51
_	Page 359		Page 361
1	but you're not going to be allowed to	1	situations. I have seen it happen before,
2	interrupt her.	2	yes.
3	MR. LOCKE: Okay. Then we'll	3	Q. The FDA asked, for example, for
4	go longer. If she's going to answer	4	then CTFA to cosponsor the 1994 workshop on
5	questions I'm not asking, then I need	5	talc, correct?
6	to go I need to be able to go	6	A. Yes, they did.
7	longer.	7	Q. The FDA knew that the report
8	MR. MEADOWS: You're not going	8	prepared by Dr. Huncharek and Dr. Muscat was
9 10	to be allowed to interrupt her.	9	based on PCPC's retention of those
10 11	That's just the bottom line.	10	consultants, correct?
12	QUESTIONS BY MR. LOCKE:	11	A. So what are you what time
13	Q. You're not a gynecological	12	period are you talking about?
	oncologist, right? A. I'm not trained as a	13	Q. Well, now, there was only one
14 15		14	time that Drs. Huncharek and Muscat submitted
15 16	gynecologic oncologist, that is true. Q. You're not a medical doctor,	15	a report to the FDA regarding talc, correct? A. So I need to look to confirm
17	Q. You're not a medical doctor, correct?	16 17	
18	A. I am not a physician, that is	18	that. Which time period are you talking about?
19	A. I am not a physician, that is correct.	19	
20	Q. Let's talk about the citizens	20	Q. 2009. Citizens petition.
21	petition.	20	A. Oh, that is true. In the
~ _	The FDA frequently seeks	21	citizens petition, that is true, yes. But I but
22	THE TUA HEQUEINLY SEEKS		
22 23	scientific information from cosmetic	1 72	
23	scientific information from cosmetic	23	Q. I mean, it says in the letter,
	scientific information from cosmetic manufacturers; is that correct? A. First part of the question?	23 24 25	Q. I mean, it says in the letter, "We're submitting a report written by Drs. Huncharek and Muscat," correct?

Page 362 Page 364 1 In the cover letter from the 1 Q. And you're not aware of any A. 2 CRE? 2 other document indicating that PCPC ever 3 From -- not CRE, from PCPC. 3 hired Drs. Huncharek or Muscat? Q. Okay. So let -- I need to -- I 4 4 A. So that's where I'll need to go need to refresh my memory on the way the 5 5 back and look at the documents, because -submissions were made. I apologize. 6 6 that I have discussed. So I need to find Do you remember which paragraph 7 7 that on my paragraph. 8 that you're referring to? 8 If you want to go off the 9 Q. Well, it's throughout your 9 record for a minute so I don't waste your report you're talking about the citizens 10 time, I will look. 10 11 petition. 11 Q. Sure. A. It's up to you. Or we can stay 12 12 A. So it's my recollection, based upon the documents that I have seen, that it 13 13 on the record. 14 was not a transparent process at all times 14 MR. LOCKE: I'm fine going off. that Drs. Huncharek and Muscat were being 15 VIDEOGRAPHER: We are going off 15 16 identified as independent consultants and 16 the record at 4:23 p.m. 17 were not ones that were being actually paid 17 (Off the record at 4:23 p.m.) by the industry for some of the work that 18 VIDEOGRAPHER: We are back on 18 19 they did. And I think that's discussed in my 19 the record at 4:25 p.m. 20 20 QUESTIONS BY MR. LOCKE: report. 21 O. Well, let's break that down. 21 Q. The question I asked: Are you 2.2 A. If you want me to confirm the 22 aware of any other document indicating that issue of the 2009 -- if you will point me to 23 PCPC ever hired Dr. Huncharek and Muscat 23 24 where you say I discuss this, I will confirm 24 other than for the 2009 response or 25 submission to the citizens petition? 25 that or not. Page 363 Page 365 1 1 Q. Well, let me break it down. A. I would have to pull this 2 Citizens petition submitted in 2 document, but in paragraph 90 I make a 3 2008, right? 3 statement: A 2005 response written by 4 A. Well, there were two: one in 4 Dr. Muscat says -- this is not '09, this is 5 5 1994 and another -- I'm sorry, 1992, and 2005, and Dr. Huncharek critiqued the work of 6 Dr. Cramer, who also failed to disclose the 6 another in 2008. 7 7 Q. Well, there are actually financial relation -- I'll start over. 8 several more than that, but let's just focus 8 Okay. So I'm sorry to repeat 9 on the 2008. 9 myself, but there was a little noise. 10 In 2008, a citizens petition 10 You asked 2009. So the other 11 was submitted? 11 time period I have in my report in 12 A. Yes, that is true. 12 paragraph 90 talks about 2005, but I'd have Q. And PCPC responded to that 13 13 to pull this document. citizens petition in 2009, correct? 14 14 But I am citing to the A. They submitted comments. Is 15 15 deposition of Dr. Loretz, who was a PCPC 16 that what you're asking me? Yes, they did. 16 employee, so I think I would need to pull 17 Yes. this in order to confirm. Q. 17 18 And that was a cover letter. 18 But I see depositions of her 19 19 correct? and Dr. Nicholson as talking about them 20 A. A cover letter -- that's all it 20 failing to disclose the financial 21 was was a cover letter? 21 relationship between their work and industry. 22 O. Well, attached to the cover 22 Q. So if Dr. Loretz did not 23 letter was a report from Drs. Huncharek and 23 testify that PCPC had retained Drs. Huncharek 24 Muscat? 24 and Muscat in 2005, you'd have no other 25 A. Yes, that is true. evidence? 25

Page 366 Page 368 1 I can't answer that 1 Q. What evidence do you have of 2 definitively, but this is what I would point 2 that? 3 you to. So I'd have to pull these documents 3 A. Based upon the close to confirm, but I have -- both paragraphs 89 4 4 interaction between PCPC, Imerys and Johnson and 90 address these general issues for you, 5 & Johnson throughout these time periods when 5 6 different actions were being taken to comment 6 but I think that's the sentence and the 7 7 documents that I think would be relevant. or to submit information on behalf of 8 But I'd have to pull them to fully answer 8 industry. 9 your question. 9 Q. Do you have a single document 10 The reason I ask the question 10 you can point to or is that an assumption? is because you frequently say "the cosmetics 11 A. That is something I seem to 11 industry" without identifying a party or a remember based on my review of these 12 12 13 person. And -- well, I'll just leave it at 13 documents, but if you need a document, I 14 would have to -- have to go and look for it. that. 14 15 And I guess the reason I'm 15 Sitting here today, you can't 16 saying I need to -- I'm questioning that it 16 recall? 17 doesn't have to do with PCPC is because I am 17 A. I can't give you a specific citing to a deposition of their employee. So 18 document as I sit here today, no. 18 I need to -- I would -- to affirm it, though, MR. LOCKE: I have no further 19 19 20 I'd need to -- I don't want to say that 20 questions. 21 100 percent the answer to your question is 21 MR. MEADOWS: Yeah, short 2.2 this is the evidence, but I believe that I 22 break. Maybe we're done, maybe we're 23 would need to go here to confirm one way or 23 24 the other. But certainly I would -- this 24 VIDEOGRAPHER: We are going off 25 raises suspicion about that for me. 25 the record at 4:30 p.m. Page 367 Page 369 1 Q. You have no evidence that PCPC 1 (Off the record at 4:30 p.m.) 2 ever retained the Center for Regulatory 2 VIDEOGRAPHER: We are back on 3 Effectiveness; is that correct? 3 the record at 4:45 p.m. A. I believe my evidence is hiring 4 **CROSS-EXAMINATION** 4 5 5 through Imerys, but let me look to make sure **QUESTIONS BY MS. PARFITT:** 6 Q. All right. Dr. Plunkett, good 6 that is true. 7 7 afternoon. I know it's been a long day. O. Why don't you look at page -or I'm sorry, paragraph 95, page 63. 8 8 Dr. Plunkett, you were asked 9 9 That's where I am. That's throughout the course of the day about 10 where I am, so let me read what I have here 10 different constituents which are part of the 11 because it's been a while since I've read 11 talcum powder products. 12 Do you recall those questions? 12 this paragraph. 13 13 Yes. So the question is, do I have in evidence this paragraph that PCPC directly 14 Q. All right. If -- without going 14 through each and every one of different 15 hired the CRE? 15 16 No, that is not provided by 16 constituents that we've talked about that are 17 this paragraph. 17 contained or could be contained in the talcum 18 Q. Okay. 18 powder products, if they are present, do 19 A. However, in this paragraph, 19 those various constituents present and 20 based on these documents that I'm seeing and provide biologically plausible evidence that 20 I'm -- my memory of what is discussed, talcum powder products can increase the risk 21 21 certainly I believe PCPC would have been 22 22 of ovarian cancer? aware of the interaction of CRE at these time 23 MS. BOCKUS: Object to the 23 24 points when I'm talking about this event --24 form. 25 these events. 25 THE WITNESS: Yes, which is --

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	Down 270	Dog 270
	Page 370	Page 372
1	I think I have a couple of paragraphs	1 CERTIFICATE 2
2	where I talk about that issue. It has	3 I, CARRIE A. CAMPBELL, Registered Diplomate Reporter, Certified Realtime
3	to do there's other information as	4 Reporter and Certified Shorthand Reporter, do
4	well, but that is a key piece of that	hereby certify that prior to the commencement of the examination, Laura Plunkett, Ph.D.,
5	information. And I focused on mode of	DABT was duly sworn by me to testify to the
6	action and additivity. That's on	6 truth, the whole truth and nothing but the truth.
7	mechanism, biologic plausibility.	I DO FURTHER CERTIFY that the
8	So the fact that you have a	8 foregoing is a verbatim transcript of the
9	variety of constituents that have a	testimony as taken stenographically by and before me at the time, place and on the date
10	known cancer hazard that share a mode	hereinbefore set forth, to the best of my
11	of action, that increases your	10 ability. 11 I DO FURTHER CERTIFY that I am
12	confidence in the biologic	neither a relative nor employee nor attorney nor counsel of any of the parties to this
13	plausibility of that relationship	action, and that I am neither a relative nor
14	between ovarian cancer and exposure to	employee of such attorney or counsel, and that I am not financially interested in the
15	tale body powders, yes.	14 action.
16	MS. PARFITT: Thank you. I	15 16
17	have no further questions. Thank you	CARRIE A. CAMPBELL,
18	very much, Dr. Plunkett. And a happy	18 NCRA Registered Diplomate Reporter
19	* * * * * * * * * * * * * * * * * * * *	Certified Realtime Reporter 19 California Certified Shorthand
20	holiday to you. THE WITNESS: Thank you.	Reporter #13921
21		Illinois Certified Shorthand Reporter
	MS. BRANSCOME: I have no	21 #084-004229 Texas Certified Shorthand Reporter #9328
22	questions.	22 Kansas Certified Court Reporter #1715
23	MS. BOCKUS: No questions.	Notary Public
24	VIDEOGRAPHER: The time now is	Dated: 12/20/18
25	4:47 p.m. This concludes the	25
	Page 371	Page 373
1	deposition, and we are going off the	1 INSTRUCTIONS TO WITNESS
2	record.	2
3	(Deposition concluded at 4:47 p.m.)	3 Please read your deposition over
4	(Deposition concluded at 1.17 p.m.)	4 carefully and make any necessary corrections.
5		5 You should state the reason in the
6		6 appropriate space on the errata sheet for any
7		7 corrections that are made.
8		8 After doing so, please sign the
9		
10		
11		same subject to the changes you have noted on
12		the errata sheet, which will be attached to
		12 your deposition.
13		13 It is imperative that you return
14		the original errata sheet to the deposing
1 🗆		
15 16		attorney within thirty (30) days of receipt
16		of the deposition transcript by you. If you
16 17		of the deposition transcript by you. If you fail to do so, the deposition transcript may
16 17 18		16 of the deposition transcript by you. If you 17 fail to do so, the deposition transcript may 18 be deemed to be accurate and may be used in
16 17 18 19		of the deposition transcript by you. If you fail to do so, the deposition transcript may be deemed to be accurate and may be used in court.
16 17 18 19 20		16 of the deposition transcript by you. If you 17 fail to do so, the deposition transcript may 18 be deemed to be accurate and may be used in 19 court. 20
16 17 18 19 20 21		of the deposition transcript by you. If you fail to do so, the deposition transcript may be deemed to be accurate and may be used in court.
16 17 18 19 20 21 22		of the deposition transcript by you. If you fail to do so, the deposition transcript may be deemed to be accurate and may be used in court.
16 17 18 19 20 21 22 23		of the deposition transcript by you. If you fail to do so, the deposition transcript may be deemed to be accurate and may be used in court.
16 17 18 19 20 21 22 23 24		of the deposition transcript by you. If you fail to do so, the deposition transcript may be deemed to be accurate and may be used in court.
16 17 18 19 20 21 22 23		of the deposition transcript by you. If you fail to do so, the deposition transcript may be deemed to be accurate and may be used in court.

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1	ACKNOWLEDGMENT OF DEPONENT	1	
2 3		LAWYER'S NOTES	
3	I do	2	
_	I,, do hereby certify that I have read the foregoing	3 PAGE LINE	
5	pages and that the same is a correct	4	-
6	transcription of the answers given by me to the questions therein propounded, except for	6	-
	the corrections or changes in form or	7 — —	-
7	substance, if any, noted in the attached	8	-
0	Errata Sheet.	9	
8 9		10	_
10		11	_
11		12	-
12	Laura Plunkett, Ph.D., DABT DATE	13	-
13	Date Date	14	-
14		16	-
15 16	Subscribed and sworn to before me this	17	-
16 17	day of, 20 My commission expires:	18	-
18		19	_
19	Notary Public	20	_
20 21		21	_
22		22	-
23		23	-
24 25		25	-
23			
1	Page 375 ERRATA		
2	ERRATA		
3	PAGE LINE CHANGE/REASON		
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Exhibit 18

UNITED STATES DISTRICT COURT DISTRICT OF NEW JERSEY

IN RE JOHNSON & JOHNSON TALCUM POWDER PRODUCTS MARKETING, SALES PRACTICES, AND PRODUCTS LIABILITY LITIGATION

THIS DOCUMENT RELATES TO ALL CASES

MDL NO. 16-2738 (FLW) (LHG)

RULE 26 EXPERT REPORT OF ARCH CARSON, MD, PHD

Date: November 16, 2018

Arch Carson, MD, PhD

Talcum Powder and Ovarian Cancer

1. Introduction

I was asked to explain the relationship between the regular perineal use of talc-based personal hygiene products and the subsequent development of ovarian cancer in their users. I intend this report to explain this relationship. I will describe ovarian cancer, what is known about its natural history, and will present statistics regarding its incidence, prevalence and fatality. I will then describe what talc is and why talcum powder is used in personal care products. I will then present the scientific evidence linking talc-based personal hygiene products and their components with cancer, and will show how the various components of this evidence, along with other data, lead me to conclude that regular perineal application of talcum powder products causes ovarian cancer in some users, and raises the risk of ovarian cancer in all users.

2. Qualifications

I am a physician who specializes in the practice of medical toxicology. I am currently an Associate Professor at the University of Texas School of Public Health in Houston and the Program Director of the Occupational and Environmental Medicine Residency training program at the University of Texas Health Science Center at Houston. I received my medical degree from the Ohio State University and a doctor of philosophy degree in Toxicology from the Kettering Laboratory at the University of Cincinnati. I am board certified by the American Board of Preventive Medicine in Occupational Medicine, and have been in the continuous practice of medical toxicology since 1991. My professional activities have included patient care, basic and applied research, teaching of medical students, graduate students and post-graduate medical trainees, and professional consulting. I have been a program director of the NIOSH-funded Education and Research Center at the University of Texas for 19 of the last 21 years. Other major collaborations include as Liaison for the World Health Organization Collaborating Centre in Occupational Health and as environmental exposure consultant to the MD Anderson Cancer Center in Houston. My curriculum vitae is attached to this report as Exhibit A.

3. Information reviewed and methodology employed

In the preparation of this report, I have reviewed relevant published scientific and medical literature, reports and documents produced in the process of litigation, and various other documents and websites that I believed to be pertinent to the refinement or extension of my professional opinions. I applied the same methodology and scientific rigor in this research that I use in my academic and clinical practice. Documents and other sources which I considered in reaching my opinions are listed in Exhibit B, "Materials and Data Considered."

4. What is ovarian cancer?

a. What is cancer?

All types of cancer involve the uncontrolled growth and accumulation or dissemination of cells that originated from normal cells, but have been altered so that they behave differently. The many cells of a single cancer that result from this change are typically all derived from a single progenitor cell, and represent a clone of cells. When this clone

reaches sufficient numbers, the cells themselves may develop into a recognizable "mass" that is called a tumor. Tumors may cause symptoms and other health problems simply by taking up space and putting pressure on neighboring structures or blocking important fluid channels or nerves, thus disrupting normal functions of the body. Still other cancers can proliferate into the blood stream. As the number of cancerous cells increase, the biochemically active substances that they produce can also become a problem resulting in abnormal biological responses throughout the body. Some substances that might become a problem in this way include normal or abnormal hormones, enzymes, antibodies, and proteins. Cancerous cells are considered malignant if they lose their normal tendency to stop proliferating when they have filled a space or the bounds of their particular tissue type, referred to as contact inhibition. Malignant cells ignore these boundary cues and may invade other tissue spaces and organs with devastating results. They may also migrate via the blood stream or other routes to distant sites within the body where they set up a new location of tumor growth and tissue invasion. This process is called metastasis. Typically, cancers are not diagnosed until they produce sufficient symptoms or biochemical abnormalities that lead to an exhaustive diagnostic search resulting in their discovery. Occasionally, cancers are discovered accidentally as part of another investigation, e.g. a chest x-ray may find an asymptomatic lung cancer; a blood test may disclose a telltale abnormality. Still fewer cancers are discovered before they cause health problems through screening tests that are sensitive and specific enough to detect common cancers at a preclinical and hopefully highly treatable stage, e.g. routine colonoscopies to detect colon cancer, or PSA blood tests to detect prostate cancer.

b. Carcinogenesis-a two-step process

The process of normal cells becoming cancer cells is generally recognized as resulting from a two-step process.

Initiation. During initiation, a change is produced at one or more places in the DNA of a cell's chromosomes. Because the DNA represents the genetic code that becomes duplicated and passed along to cells that arise from it, when that cell divides to produce two cells, the change to the genetic code is also duplicated and is present in both of them.

Normally, the abnormal cell that results from a change in the genetic code cannot survive because its cellular machinery is also abnormal and poorly or non-functional. Less often, if the cell is able to survive in the body, it is still abnormal and deformed, and is recognized by the body's immune system as alien. The immune system attacks it and destroys it, and it does not survive. In the very rare instance that an alteration to the genetic material results in a survivable hereditary change that is not fatal, and which can escape the surveillance of the body's immune system, the resulting clone may live and persist. (Coussens LM, 2002)

Promotion - Once a cancer clone has been produced, it is at risk for being discovered and destroyed by the body's immune system, or failing to thrive in an environment for which it is not suited. Promotion is the process by which the cancer clone is shielded

from the body's defenses and is stimulated to undergo rapid growth, transforming a microscopic cancer clone into a self-sustaining symptomatic cancer over time. (Ferrante D, 2007) (Coussens LM, 2002)

Most known carcinogenesis events occur by the two-step process and involve a long latent period between the moment of the alteration in the genetic material and the recognition that a cancer is present. In human cancers, this latent period is often several months to many years in length. The latency period for ovarian cancer, generally, and for cancers induced by environmental agents is usually quite long, often >20 years. (Nadler DL, 2014) Promotion occurs throughout the latent period and stimulates the growing cancerous cells to become a recognizable cancer. A third stage in the natural history of a cancer, referred to as Progression, involves maturation, differentiation or dedifferentiation and accumulation of transcriptional changes that solidify the tumor's growth rate and invasiveness. Some carcinogenic substances are initiators and some are promotors, and still others are called complete carcinogens because they are capable of initiation and promotion.

c. Ovarian cancer

Ovarian cancer is a group of cancers that arise in the ovary or in adjacent tissues. It is estimated that about 22,240 women will receive a new diagnosis of ovarian cancer and about 14,070 women will die from ovarian cancer in the United States in 2018. (American Cancer Society, n.d.) (Torre LA, 2018) Ovarian cancer ranks fifth in cancer deaths among women, and first due to cancers of the female reproductive system. Most ovarian cancers are not discovered until they have reached an advanced stage and have spread to sites elsewhere in the body. Because advanced ovarian cancers are more difficult to treat, they have a high fatality rate. For these reasons, any effective prevention of ovarian cancer or reduction in ovarian cancer risk can have a significant impact on this disease and can save many women's lives.

There are several recognized forms of ovarian cancer that are distinguished by the specific tissues from which they arise, or the microscopic characteristics of the tumor cells themselves. About 85% to 90% of malignant ovarian cancers are epithelial ovarian carcinomas, and the majority of these are of the serous type (American Cancer Society, n.d.) (Prat, 2015). Ovarian, fallopian tube, and peritoneal cancers have a similar clinical presentation and are treated similarly, and current evidence suggests that they may have a common origin, supporting a common staging system (Soong TR, 2018).

Despite significant advances in cancer diagnosis and therapies over the past several decades, there have been few changes in the incidence or fatality rates for ovarian cancer. Consequently, it is worth considering preventable environmental causes of the ovarian cancer epidemic. (Woodruff, 1979) (LA Torre, 2018)

5. What is talc?

a. General

Talc is a hydrated magnesium silicate mineral produced through a metamorphic geological process and having the generalized chemical formula Mg₃Si₄O₁₀(OH)₂. Some substitution of atoms occurs in variations of talc found in nature. Small amounts of Aluminum (Al) or Titanium (Ti) can substitute for Silicon, and small amounts of Iron (Fe), Manganese (Mn), Aluminum (Al) and Calcium (Ca) can substitute for Magnesium. This produces slight variations in the color, hardness and chemical properties of the mineral. Talc is the softest mineral on the Mohs Hardness Scale. (King, n.d.) It is essentially insoluble in water, but is slightly soluble in dilute mineral acids. The process seems to involve the extraction of magnesium and other cations leaving only the silicate as silicic acid and silica.

The commercial value of talc stems from its crystalline structure. Most talc is present in natural deposits as the platy form of talc, in which the talc crystals are arrange in large flat sheets running parallel to one another. These sheets are attracted to each other by weak Van der Waals forces that can be easily overcome by mechanical forces, causing the sheets to slide on each other. On the macro scale, this property gives talc its characteristic slippery feeling on the skin. The platy structure also gives talc its ability to absorb moisture and oil. Some talc is found as a fibrous crystalline structure, similar to some asbestos, also a magnesium silicate mineral. In fact, these two minerals are closely related in terms of their formation and composition. Talc deposits are often intermingled with asbestos and vice versa. (Rohl, 1974) (Rohl AN, 1976) (National Institute for Occupational Safety and Health, 2011) (Lockey, 1981)

b. Talcum Powder and Cancer.

Numerous studies have examined the cancer causing characteristics of talc. (Wild, 2006) Talc has caused cancer when implanted in various tissues and under the skin in laboratory animals. It causes inflammation and fibrotic reaction, including the chemotaxis of inflammatory immune cells, and accelerated growth and division of cells in the involved tissues (Okada, 2007). This is a normal body process that leads to the thwarting of infection and rapid healing, but in the absence of tissue injury, accelerated growth and cell division has the effect of amplifying and propagating viable genetic mutations, leading to cancer. Talc particles have been repeatedly demonstrated in ovarian tumor tissues (Henderson WJ C. J., 1971) (Henderson WJ T. H., 1979) and in inflammatory tissue in otherwise normal ovaries (Mostafa SAM, 1985). In 2006, the International Agency for Research on Cancer (IARC) evaluated the published evidence for the carcinogenicity of talc, not containing asbestiform fibers, when inhaled into the respiratory system and when applied to the perineum in personal hygiene activities. The agency concluded that talcum powder is a "possible human carcinogen" (Group 2B) when applied to the perineum, meaning that there is insufficient evidence of carcinogenesis in humans, but strong evidence in other mammalian species. IARC also concluded that there was insufficient evidence of carcinogenicity by the inhalation route (Group 3). (International Agency for Research on Cancer, 2010) Since that time,

numerous other studies have added to the data on this issue. A recent meta-analysis showed that talc workers do have an excess of lung cancers. (Chang C-J, 2017)

When implanted under the skin or into tissues of laboratory animals, talcum powder induces an inflammatory response. This reaction involves the chemotaxis of inflammatory cells of the immune system, lymphocytes, neutrophils and macrophages, the release of cytokines that promote membrane permeability and stimulate cell division. As this reaction matures over time, granulomas may begin to develop. All of this signifies that talcum powder is an effective and potent promotor of already initiated genetic alterations. (Fletcher NM M. I., 2018) (Fletcher NM S. G., 2018) (Saed GM, 2017) (Radić I, 1988) (Okada, 2007) Other studies have demonstrated the ability of these same reactions to satisfy the carcinogenic initiation step, characterizing talcum powder as a complete carcinogen. (Shukla A, 2009) (Fletcher NM M. I., 2018)

c. What about asbestos and other components in talc and talc-based products?

Talcum powder products in the marketplace have been shown to contain asbestos. (Paoletti L, 1984) (VanOrden D, 2000) (VanGosen BS, 2004) (Longo WE, 2017) Asbestos is conclusively recognized as a cause of ovarian cancers. The IARC Working Group concluded that "a causal association between exposure to asbestos and cancer of the ovary was clearly established, based on five strongly positive cohort mortality studies of women with heavy occupational exposure to asbestos, (International Agency for Research on Cancer, 2012)" and "studies showing that women and girls with environmental, but not occupational exposure to asbestos had positive, though nonsignificant, increases in both ovarian cancer incidence and mortality. (Acheson ED, 1982) (Fox, 1982) (Berry G, 2000) (Newhouse ML, 1972) (Reid A H. J., 2008) (Reid A S. A., 2009) (Pira E, 2005) (Magnani C, 2008) (Bertolotti M, 2008) (Ferrante D, 2007) (Germani D, 1999) (Rösler JA, 1994) The classification determined by IARC included all forms of asbestos and talc containing asbestiform fibers (fibrous talc). I have seen evidence that Johnson & Johnson's talcum powder products contain asbestos and fibrous talc. ¹

d. Carcinogenic metals in talcum powder

In addition to other related minerals, talcum powder may contain varying amounts of chromium, cobalt and nickel, metal ions that are recognized as cancer causing. These ions leach out of the talcum powder slowly over time, resulting in continuous, low-level exposure of the surrounding tissues to carcinogenic metals. (Jurinski JB, 2001) I have seen evidence that Johnson & Johnson's talcum powder products contain nickel (Group 1

¹ Ex. 28, Hopkins Dep. (Aug. 16 & 17, 2018; Oct. 26, 2018; and Nov. 5, 2018); Ex. 47, Pier Dep. (Sept. 12 & 13, 2018); Expert Report of William E. Longo, PhD and Mark W. Rigler, PhD (Nov. 14, 2018)

human carcinogen), chromium (Group 1 human carcinogen), and cobalt (Group 2B-possible human carcinogen). ²

e. Other potentially cancer-causing constituents

Johnson & Johnson's Baby Powder and Shower to Shower contain numerous ingredients that have been added to the products, i.e. fragrance chemicals, some of which have been shown to produce cancer in laboratory animals. These substances are likely to be present in very small or trace quantities, and likely present a lower level of risk than the major components, by mass. Nonetheless, any additional risks are added as part of a total risk profile. I have reviewed the report of Dr. Michael Crowley and agree with his conclusions that these chemicals may contribute to the inflammatory properties, toxicity, and potential carcinogenicity of the products.³

6. Epidemiology linking talcum powder and ovarian cancer

Many research studies have shown a strong association between talcum powder exposure and the development of ovarian cancer. (Langseth H, 2008) (Terry KL, 2013) (Schildkraut JM, 2016) (Trabert, 2016) (Berge W, 2017) (Cramer Daniel W, 2016) (Penninkilampi R, 2018)

a. What evidence links exposure to talcum powder products with ovarian cancer?

Multiple epidemiological studies have examined the link between the personal hygiene use of talc containing products and the occurrence of ovarian cancers (Booth M, 1989) (Cook LS K. M., 1997) (Cook LS e. a., 1997) (Cramer DW, 1982) (Whittemore AS, 1988) (Harlow BL W. B., 1989) (Chen Y, 1992) (Harlow BL C. D., 1992) (Rosenblatt KA, 1992) (Hartge P, 1988) (Tzonou A, 1993) (Chang S, 1997) (Heller DS, 1996) (Penninkilampi R, 2018). Talcum powder causes proliferation of human (Prat, 2015) ovarian cells in culture (Buz'Zard AR, 2007), and causes these cells to express reactive oxygen species (ROS) (Buz'Zard AR, 2007).

The research investigating the link between talcum powder exposure and ovarian cancer has been reviewed as a scientific whole at multiple stages. (Harlow BL H. P., 1995) (Ness Roberta B, 1999) (Muscat JE, 2008) (Terry KL, 2013) (Berge W, 2017) (Penninkilampi R, 2018)

Laboratory, animal and human studies support the conclusions that talc causes ovarian cancer, and have filled in the blanks that establish biological plausibility and scientific coherence. (Jaiswal M, 2000) (Balkwill Fran, 2001) (Okada, 2007) (Saed Ghassan M, 2017) (Harper, 2019)

7. Talcum powder product use

² Ex. 47, Pier Dep. (Sept. 12 & 13, 2018)

³ Expert Report of Michael Crowley, PhD (Nov. 12, 2018).

Numerous studies have interviewed women regarding their personal practices of application of talc-based powders to the perineal area. Due to variations in these practices, it has been difficult to estimate dose in order to evaluate the dose response relationship for ovarian cancer. It is also difficult to exactly estimate the quantity of talcum powder administration during personal hygiene activities. For studies that attempted to determine amount of exposure, most relied on a method of estimating the frequency of application and/or the duration of those practices, then simply multiplying to reach a total number of applications over time. (Harlow BL H. P., 1995) (Langseth H, 2008) A review of studies of perineal talcum powder or cornstarch application suggests that the use of cornstarch instead of talcum powder reduces the risk of ovarian cancer. (Whysner J, 2000)

8. Other evidence

a. Transport of talc-containing materials from the perineum to the upper reproductive tract and body cavities has been shown to occur with startling regularity and with respect to a wide variety of particulate materials. (Egli GE, 1961) (Venter PF, 1979) (Blumenkrantz MJ, 1981) (Halme J, 1984) (Sjösten ACE, 2004) Clearly, sufficient particulate materials applied routinely to the perineum have ready access and in sufficient quantities to produce biological responses in internal tissues, including the ovaries and surrounding structures. There are a limited number of animal studies suggesting that this transport does not occur. (National Toxicology Program, 1993) These are not as compelling as the human evidence because of anatomical and physiological differences between animals and humans in this regard, as well as the overwhelming evidence in humans.

9. Conclusions and opinions

The following conclusions and opinions are expressed with respect to reasonable medical and scientific certainty and I have applied reliable scientific principles and methods to the facts in reaching them. These opinions are based upon the documents and literature reviewed and cited herein, and also upon my own professional training and experience in practice of medicine and medical toxicology.

I. Talcum powder products sold for personal hygiene use are carcinogenic.

Talcum powder is immunogenic, producing chronic inflammation in the tissues in which it sequesters, with the attraction of lymphocytes and macrophages and the ongoing local release of pro-inflammatory cytokines and reactive oxygen species. Further, all talcum powder has some component of mineral fibers that are toxic to macrophages and intensify the inflammatory response and stimulate cell growth and proliferation. The presence of asbestos, fibrous talc, carcinogenic metals and other chemicals further intensify this effect. Cohort and case-control studies have shown statistically significant associations between talc-based powder use and ovarian cancers. The presence of carcinogenic metals such as, chromium, cobalt and nickel, and toxic fragrance components in commercial talcum powder products, adds to their carcinogenic potency. Talcum powder is a complete carcinogen and can both initiate and promote the development of cancers in the tissues in which it sequesters.

II. Perineal use of talcum powder products for feminine hygiene purposes results in direct exposure to the female reproductive tract.

A proportion of talcum powder from personal hygiene applications to the perineum is transported or migrates through the reproductive tract, through the patent fallopian tubes, onto the ovaries and into the pelvic cavity. Talc particles have been identified in reproductive system structures of women who utilize talc powders. These include the uterine cervix, the endometrium, the fallopian tubes and the ovaries. Inhalation is likely a secondary route of exposure.

III. Common carcinogenic constituents of talcum powder products participate in and add to the carcinogenic process.

Naturally occurring carcinogenic components of talcum powder, i.e. asbestos, chromium, nickel, and cobalt, are liberated in bodily fluids and tissues and are free to exert their carcinogenic effects. Added substances that are toxic or carcinogenic, i.e. fragrance chemicals, may also contribute to these effects. This process is the most intense where the duration is the longest. Because the ovaries have no intrinsic elimination system, the transport of talc particles and their constituents reaches the ovaries where it stalls and sequesters. For these reasons, ovarian tissue is most at risk for the carcinogenic effect of these substances.

IV. Regular perineal application of talcum powder products causes epithelial ovarian cancer in some users, and raises the risk of ovarian cancer in all users.

Multiple case-control and cohort epidemiological studies have looked at the relationship between the perineal use of talc-based powders and the eventual development of epithelial ovarian cancer. Most, but not all, of these studies show a consistent positive relationship. When confounding and bias are exhaustively considered, the positive association remains. I conclude that the apparent cause and effect relationship between perineal talcum powder use and ovarian cancer is real, amounting to about a 30% increased risk of ovarian cancer in talcum powder product users. At the current rate of ovarian cancer diagnosis and mortality, elimination of this source of risk could result in over 3,000 lives saved in the U.S. each year.

In 1965, Sir Austin Bradford Hill published what has come to be recognized as the best collection of factors to consider for the assessment of scientific evidence that relates the causation of disease to environmental exposures (Hill, 1965). These factors include: (1) Strength of association, (2) Consistency of the evidence, (3) Specificity, (4) Temporality, (5) Biological gradient, (6) Plausibility, (7) Coherence, (8) Experiment, and (9) Analogy. Below I provide my evaluation of the scientific evidence with respect to the Hill factors.

Strength of association –Many epidemiological studies have attempted to examine the association between perineal use of talcum powder products and ovarian cancer. Most of these have been case-control studies, where women diagnosed with ovarian cancer are paired with others of similar demographic background who do not have ovarian cancer. All of these women are interviewed about their past practices and exposures, including the use of talcum powder products. The resulting data are analyzed to compute an odds ratio (OR) that describes the

likelihood of those with cancer having had greater exposure to talcum powder than those who did not. Cohort studies selected populations of women, assessing them for many factors, including perineal talcum powder use, and followed them over time counting the occurrences of ovarian cancers. These studies were than able to compute a relative risk (RR) of exposure to talcum powder resulting in ovarian cancers. Of more than 25 case-control studies in the literature, the heavy majority showed positive and significant ORs for perineal talcum powder use and ovarian cancer. The three cohort studies did not find a significant relative risk of perineal talcum powder exposure leading to ovarian cancer, but did show positive non-significant trends. Several research groups have looked at the totality of the research evidence, evaluated the published study reports, and have reanalyzed those data on a common playing field through meta-analyses. Taken in their totality, and accounting for sources of bias and differing statistical treatments, these epidemiological studies support a strong association between the perineal use of talcum powder and ovarian cancer.

Consistency of the evidence – As stated above, the majority of epidemiological studies that have investigated the link between perineal talcum powder use and ovarian cancer have reported positive associations. These studies are consistent in their findings of a relationship between perineal use of talcum powder products and the development of ovarian cancer. Further, recent meta-analyses of previously published studies have verified the comparability of the research methods used and the consensus of conclusions.

Specificity – Specificity is the concept that a specific disease, rather than a host of diseases, is produced by a particular exposure, and that the exposure is a principal cause of the disease. Although talcum powder is known to cause non-specific inflammation in many tissues where its residues locate, the stimulation of ovarian cancer is particularly associated with the presence of talc in the ovaries and fallopian tubes. Of known factors associated with ovarian cancer, i.e. nulliparous state, early menarche, late menopause, oral contraceptive use, living in the twentieth century and beyond, perineal talcum powder exposure is proving to be prominent among them.

Temporality – If a particular exposure is the cause of a particular disease, then the onset of exposure should precede the onset of the disease. Studies investigating the link between perineal talcum powder exposure and ovarian cancer are designed to compare those with prior exposure to those who are not exposed, and so the scientific evidence supports this consideration.

Biological gradient – A basic toxicological principle is that a greater exposure intensity will result in a larger proportion of those exposed expressing the toxic effect, in this case ovarian cancer. In order to determine the intensity of a long-term environmental exposure, typically a measure of frequency or quantity of use is multiplied by the duration of such use. This allows categorization of exposure levels and comparisons. Although some studies have failed to find evidence of a dose-response relationship, several more recent reports have shown a clear dose-response when the number of subjects rose to a level producing sufficient statistical power to allow the analysis after subdivision of subjects into pertinent categorical groups, and frequency and duration were measured (Schildkraut JM, 2016) (Cramer Daniel W, 2016) (Wu, et al., 2009).

Plausibility – This factor expects the rational presentation of a mechanism whereby the exposure in question leads to the disease. Thus, if no such mechanism can be proposed, it is less likely that causation will be supported. In the case of ovarian cancer, the mechanism supported in the literature is as follows: Talcum powder products are applied to the perineal area in the course of routine personal hygiene practices. This element is supported by the existence of these products in the marketplace for many years and the statements of subjects interviewed for the purpose of conducting the scientific research discussed elsewhere in this report. Portions of the applied powders are transferred via active processes or passive mass action movements into the female reproductive tract, some making it all the way to the distal fallopian tubes, the ovary surfaces and the pelvic and peritoneal cavities. This element is supported by the observations that particulate materials of differing variety can make their ways along these pathways to the listed destinations, and the finding and confirmation of talc particles in normal ovarian tissues and ovarian tumor tissues at the time of oophorectomy or autopsy. Once reaching the target tissues, talcum powder and its constituents initiate carcinogenesis via multiple means, including, inflammation with chemotaxis of inflammatory cells, liberation of cytokines, and reactive oxygen species, inactivation of TP53 genetic modulator, inhibition of DNA repair, and long-term promotion of genetic mutations via continuous inflammation and cellular growth stimulation.

Coherence – The proposed cause and effect relationship should not "seriously conflict with the generally known facts of the natural history and biology of the disease."(Hill, 1965) The proposal that talcum powder product use results in the occurrence of ovarian cancer is entirely consistent with what is known about other factors related to ovarian cancer, i.e. early menarche, late menopause, pregnancies, breastfeeding history, oral contraceptive use, etc. All are factors that influence the local inflammatory environment of the ovary and its surroundings and have the potential to promote existing transcriptional errors and mutations.

Experiment – Interventions, such as tubal ligation that decreases the incidence of ovarian cancer by blocking the exposure route, offers experimental support for this mechanism. The use of cornstarch-based dusting powders as a substitute for talcum powder products offers additional experimental support.

Analogy – Have there been other environmental exposures that have been associated with ovarian cancers that act via similar mechanisms? Talcum powder is somewhat unique in terms of its delivery mechanism. But beyond that, the case of asbestos exposure is similar. Asbestos exposure has resulted in excesses of ovarian cancers in exposed women, although the route of exposure is thought to be by inhalation. Nonetheless, asbestos is a mineral very similar both chemically and structurally to talc that has been found in the ovary and peritoneal cavity of exposed women. The mechanisms of carcinogenesis for both asbestos and talc are similar and analogous. Further, talc-based products contain asbestos and non-asbestos mineral fibers having carcinogenic potential.

When considering these factors, I gave the most weight to the compelling strength of association and consistency, as well as the well-described biologic mechanism.

The currently available scientific research, when considered in its totality, demonstrates a cause and effect relationship between the use of talcum powder products and the development of epithelial ovarian cancer. This opinion is reinforced by my consideration of the Hill factors for the assessment of causation.

In reviewing the scientific and medical literature on talcum powder product use, I also performed a risk assessment and considered whether perineal use of those products poses a safety risk to consumers. This involved careful consideration of the epidemiological literature, data on the dose-response relationship and exposure, as well as the nature of these products, which are used primarily for personal care. I also considered evidence of the toxicity of these products, for which repeated testing and analyses have shown to contain carcinogens.

In considering the weight of this epidemiologic, toxicologic, and mechanistic evidence, across multiple studies, time, demographics, and researchers, demonstrating a consistent association between perineal use of talcum powder products and ovarian cancer, it is my opinion that talcum powder products increase the risk of ovarian cancer and pose a significant health hazard.

In conclusion, it is my opinion that the perineal use of talcum powder products causes ovarian cancer in some users and increases the risk of ovarian cancer in all users of these products.

All of my opinions in this report are provided with respect to a reasonable degree of medical and scientific certainty. I reserve the right to amend or supplement my report as new information becomes available.

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Exhibit A

Curriculum Vitae

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Biosketch

Arch "Chip" Carson, MD, PhD is a physician (The Ohio State University), board certified in Occupational Medicine (American Board of Preventive Medicine), who holds a Doctor of Philosophy degree in Toxicology (University of Cincinnati, Kettering Laboratory). He has served on the faculty of the University of Cincinnati and the New York University Medical Center and joined the faculty of the University of Texas School of Public Health in 1992 in its Environmental Sciences Discipline and Occupational and Environmental Health and Aerospace Medicine Module. He is Associate Professor of Occupational Health, directs the Occupational and Environmental Medicine Residency Program and is a member of the research team of the Southwest Center for Occupational and Environmental Health, a NIOSH Education and Research Center, and WHO Collaborating Centre in Occupational Health. He maintains a clinical practice of occupational medicine and medical toxicology. In his more recent role as Medical Director for the University of Texas Medical Branch in Galveston, he is responsible for the health monitoring and care of more than 15,000 employees. He is a frequent consultant to governments, corporations and the legal community on matters related to industrial chemical exposure, toxicology and environmental justice. His research interests include: environmental and occupational chemical exposures, inhalation injuries, metal exposures and cancer, and professional training in occupational medicine.

Professional Activities/Employment

2017-18	University of Texas Medical Branch, Galveston, Assistant Clinical Professor of Preventive Medicine and Family Medicine
2017-18	University of Texas Medical Branch, Galveston, Medical Director, Employee Health Services.
2017-18	Enbridge Corporation, Houston Texas, Medical Director, Employee Health Services.
2010-18	University of Texas Health Science Center, Houston, Associate Professor of Occupational Health.
2010-18	University of Texas Health Science Center at Houston, Program Director, Occupational and Environmental Medicine Residency.
1991-18	Private practice of Occupational Medicine and Toxicology, New York, Texas and Ohio.
2011-18	Spectra Energy Corporation, Houston Texas, Medical Director, Employee Health Services.
1997-13	Texas Medical Center Inc., Houston Texas, Medical Director, Employee Health Services.
1992-08	University of Texas School of Public Health, Assistant Professor of Occupational Medicine and Environmental Sciences.
1998-08	University of Texas Health Science Center at Houston, Program Director, Occupational and Environmental Medicine Residency.
2003-08	Southwest Center for Occupational and Environmental Health, Principal Investigator and Director, Diller Phosgene Exposure Incident Registry of the American Chemistry Council.

2000-06	Chevron Phillips Chemical Company, Houston Texas, Corporate Medical Director.
2003-05	U.S. Department of Energy Office of Worker Advocacy Physician Review Panel Appointee.
1997-04	Southwest Center for Occupational and Environmental Health, Principal Investigator, City of Houston Lead Poisoning Epidemiology Project.
1992-03	UT Health Services, University of Texas Houston Health Science Center, Attending Physician, Occupational Medicine and Toxicology.
1997-01	University of Houston Downtown, Medical Director, Student Health Service.
1998-99	University of Texas School of Public Health, Convener of the Occupational/Environmental Health and Aerospace Medicine Module.
1992-97	Respiratory Consultants of Houston, PA, Attending Physician, Occupational Medicine and Toxicology.
1992-95	Exxon Chemical Americas, Baytown Polymer Center and Basic Chemicals Technology, Baytown TX, Consultant Physician.
1990-91	New York University Medical Center, Bellevue Hospital, Tisch Hospital, and Manhattan VA Hospital, New York NY, Dept. of Medicine, Clinical Instructor.
1982-90	Chemical Information Services Inc, Cincinnati OH, Associate in Toxicology.
1978-87	University of Cincinnati College of Medicine, Cincinnati OH, Instructor and Lecturer, Adjunct Assistant Professor of Industrial Toxicology.
1974-79	University of Cincinnati College of Medicine, Kettering Laboratory, Cincinnati OH, Research Technologist in Occupational Medicine and Clinical Studies.
1969-74	Millstone Inc., Cincinnati OH, Design Engineer, environmental control systems.
Educational B	ackground
2002	Certificate of Board Eligibility, Medical Toxicology, American Board of Preventive Medicine/American Board of Emergency Medicine
1992	Certificate of Training - Residency in Occupational Medicine University of Texas Health Science Center at Houston, School of Public Health, and Southwest Center for Occupational and Environmental Health, Houston TX, 1992.
1991	Certificate of Training - Postgraduate Internship in Internal Medicine, New York University Medical Center and Bellevue Hospital Center, New York NY.
1990	MD - Ohio State University College of Medicine, Columbus OH.
1987	PhD - Kettering Laboratory, University of Cincinnati College of Medicine, Cincinnati OH, awarded in the field of "Environmental Health – Toxicology."
1973	BS - University of Cincinnati College of Arts and Sciences Cincinnati OH. Awarded in "Biological Sciences with Concentration in Engineering."
1969	Rensselaer Polytechnic Institute, Troy NY. Management Engineering
1968	Villa Madonna College, Covington KY. Certificate in Contemporary Physics.
Fellowships	
2011-13	UTHealth, Health Educators Fellowship, University of Texas Health Science Center at Houston.

1983-85	American Lung Association Fellowship in Lung Research (Inhalation Toxicology), American Lung Association of Southwestern Ohio, Grant.
1981-82	Owens Corning Fiberglas, Graduate Research Fellowship in Combustion Toxicology.
1979-80	National Institute for Occupational Safety and Health, Centers for Disease Control, Doctoral Fellowship in Industrial Toxicology.
Certifications	
2012	License to practice medicine, State of Ohio 35.098635
2010	Certified Healthy Homes Specialist – National Environmental Health Association.
2002	Board Eligibility, Medical Toxicology, American Board of Preventive Medicine/American Board of Emergency Medicine.
1994	Board Certification, Occupational Medicine, American Board of Preventive Medicine.
1992	License to practice medicine, State of Texas J2524.
1991	License to practice medicine, State of New York 186563.
1982	Emergency Hazard Response, Environmental and Industrial Chemical Accident Management, U.S. Environmental Protection Agency.
1979	Pulmonary Function Testing for Occupational Surveillance, NIOSH #003.
Professional C	Community Service
2013-18	University of Texas Health Science Center at Houston, Steering Committee on Interprofessional Collaboration
2013-18	University of Texas Health Science Center at Houston, Chemical Safety Committee.
1998-18	Association of Environmental and Occupational Clinics/ATSDR community resource on toxic exposures and health consequences, Federal Region VI.
1997-18	City of Houston Biological, Chemical and Radiation Emergency Preparedness Program. Medical Toxicology On-Call Advisor to the Houston Medical Strike Team.
1998-18	Association of Occupational and Environmental Medicine Residency Directors. Chairman 2005-2006
2010-18 1997-08	University of Texas Health Science Center at Houston, Graduate Medical Education Committee
2010-18 1994-08	University of Texas Health Science Center, Houston, Community/Press Resource and Speaker via Public Information Office, (Toxic Exposures and Environmental Health).
1996-18	American College of Occupational and Environmental Medicine, Council on Academic Affairs and Co-chair, Academic Section 2004-2006. Occupational Medicine Residency Directors Committee, Chair 2006-2007, Appointed Member, Taskforce on the Future of Occupational Medicine Education 2005-2007. Appointed Co-chair, Taskforce on the Future of Occupational Medicine Education 2013-2015.
1996-18	Texas College of Occupational and Environmental Medicine. Secretary/Treasurer-2004-5, President Elect-2005-6, President-2006-7, Past President 2007-8.
2003-12	Boy Scouts of America, Sam Houston Council, Registered Adult Leader and Merit Badge Counselor.
2005-08	University of Texas School of Public Health, Practice Council Co-chair

2003-05	U.S. Department of Energy Office of Worker Advocacy Physician Review Panel Appointee.
1996-00	American Public Health Association, Occupational Health Subcommittee
1994-96	Advisory Board, National Environmental Education and Training Center (NEETC), Curriculum Development Committee.
1981-85	Tri-State Air Committee Inc., Cincinnati OH, (voluntary air quality organization) Scientific Advisor, Elected to Board of Directors in 1982, President and Chairman 1984-85.
1981-85	American Lung Association of Southwestern Ohio, Cincinnati OH, (voluntary health organization) speakers bureau.
1982-83	City of Cincinnati, Appointment to Occupational Health Scientific Liaison Board (municipal advisory committee).
1981-83	Cincinnati Area Toxic Substances Coalition, Cincinnati OH, (coalition of business, voluntary, and labor organizations with interest in environmental toxic substance issues) Cofounder and Chairman.
1982-83	Ohio River Valley Committee on Occupational Safety and Health, Cincinnati OH, (organized labor coalition) Scientific Resource Committee.
1972-82	Walnut Hills-Evanston Medical Center, Cincinnati OH, (primary care center) Board of Directors.

Professional Societies

1991-18	American College of Occupational and Environmental Medicine.
1991-18	Texas College of Occupational and Environmental Medicine
2007-18	Texas Public Health Association.
2006-18	International Congress on Occupational Health.
2003-18	American College of Medical Toxicology.
2002-06	Society of Occupational and Environmental Health.
2001-06	American Conference of Governmental Industrial Hygienists.
1994-00	American Public Health Association.
1983-87	American Industrial Hygiene Association.
1983-87	Society of Toxicology.
1980-85	American Thoracic Society, Associate Member and Participant in Occupational and Environment Scientific Session.

Publications

Anderson F, **Carson A**, Whitehead L and Burau K Age, Race and Gender Spatiotemporal Disparities of COPD Emergency Room Visits in Houston, Texas. Occupational Diseases and Environmental Medicine. 3:1-9, 2015. http://dx.doi.org/10.4236/odem.2015.31001.

Anderson F, **Carson A**, Whitehead L and Burau K. Spatiotemporal Analysis of the Effect of Ozone and Fine Particulate on CVD Emergency Room Visits in Harris County, Texas. Open Journal of Air Pollution, 3:87-99, 2014. http://dx.doi.org/10.4236/ojap.2014.34009.

Calcote, JC, **Carson, A**, Peskin, MF, Emery, RJ. An assessment of post-disaster psychological stress in hazardous waste operations and emergency response (HAZWOPER) workers. Disaster Med Public Health Preparedness. 7:452-460, 2013. PMID 24274124.

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Pugach S, Clarkson T, (**Carson A**). Prenatal mercury exposure and postnatal outcome: clinical case report and analysis. Clin Toxicol 47:366-370, 2009.

Pauluhn J, **Carson A**, Costa DL, Gordon T, Kodavanti U, Last JA, Matthay MA, Pinkerton KE and Sciuto AM. Workshop summary: phosgene-induced pulmonary toxicity revisited: appraisal of early and late markers of pulmonary injury from animal models with emphasis on human significance. Inhalation Toxicology. 19(10):789-810, 2007.

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Nooka A, Duonghi L, **Carson A**, Hassan M. Assessing Occupational Risk for Pancreatic Cancer by Chemical Exposures and Work History: A Case-Control study at MD Anderson Cancer Center. American Association for Cancer Research, Orlando. March, 2004.

Mitchell CS, Moline J, Avery AN, Baker D, Blessman JE, **Carson A**, Cosby O, Darcey D, Ducatman A, Emmett EA, Forst L, Gerr F, Gochfeld M, Guidotti TL, Harber P, Hu H, Hegmann KT, Kipen HM, Levin J, McGrail MP, Meyer JD, Mueller KL, Prince S, Rubin R, Schwerha JJ, Sprince NL, Taiwo O and Upfal M. In response to the 2002, vol. 22, no. 4 article entitled "The rise and fall of occupational medicine in the United States" [Letter] Am J Preventive Med. 23(4):307-9, 2002.

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Bright K, Delclos G, **Carson A**, Felknor S, Mackey T, Morandi M, Schultz L and Whitehead L. A Global Study of Occupational Health Competencies and Curricula, Report to the World Health Organization, March, 2000, Southwest Center for Occupational and Environmental Health.

Carson A, Guevara E, Delclos GL, Murray KA, Burau KD, Morandi MT, Felknor SA, ("A Study of General Health of Workers of the Industrial Complex of Barrancabermeja") in [Compendium on Occupational Health in the Petroleum Industry of Colombia: Technical and Scientific Report of the "Occupational Health in the Petroleum Industry" Project], 1999 Pan American Health Organization (co-author).

Carson A, Hangoc V and Bahrainwala M, City of Houston Childhood Lead Poisoning Prevention Program: Case Density and Impact Analysis, June 30, 1999, Technical Report (Principal Investigator).

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Vinegar A, **Carson A** and Pepelko WE, "Pulmonary Function Changes in Chinese Hamsters Exposed to Diesel Exhaust," in Health Effects of Diesel Engine Emissions, Vol. 2, WE Pepelko, RM Danner and NA Clarke eds, 1980, US Environmental Protection Agency, Washington.

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Elia VJ, Anderson LA, MacDonald TJ, **Carson A**, Buncher CR and Brooks SM, "Determination of Urinary Mandelic and Phenylglyoxylic Acids in Styrene Exposed Workers and a Control Population," Am Ind Hyg Assoc J, 41:922-926, 1980.

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DEPOSITIONS, TRANSCRIPTS AND REPORTS:

Affidavit of Laura Plunkett, PhD 02.22.18 Deposition of Alice Blount in the Ingham v. J&J Matter on 04.13.18 Deposition of Annie Awanais Yessian on 07.13.2017 Deposition and Exhibits of Pat Downey Dated 8.7.18-8.8.18

Deposition and Exhibits of John Hopkins Dated 8.16.18-8.17.18, 10.17.18 and 11.05.18

Deposition and Exhibits of Susan Nicholson Dated 7.26.18-7.27.18

Deposition and Exhibits of Julie Pier Dated 9.12.18-9.13.18

Ingham v. J&J Volume 11 (Egilman, Koman, Martinez, Packard) 6-14-18

Ingham v. J&J Volume 14A (Madigan, Williams) 6-20-18

Ingham v. JJ Volume 24A (Warner Huh, MD) 7.5.18

Ingham v. JJ Volume 24B (Warner Huh, MD) 7.5.18

John J. Godleski Expert Report for Brower Matter Dated 6.23.18

Lanzo Plaintiffs MIL re Imerys Spoliation and Concealment of Talc Samples

Laura Plunkett - Supplemental Expert Brower Report

Longo Analysis of J&J's Historical Talc Samples from the 1960's

Longo Analysis of J&J's Historical Talc Samples from the 1970's

Longo Analysis of J&J's Historical Talc Samples from the 1980's

Longo Analysis of J&J's Historical Talc Samples from the 1990's

Longo Analysis of J&J's Baby Powder Historical Samples - Asian - October 2018

Longo Analysis of J&J's BP Talc Products for Amphibole (Tremolite) Asbestos 8.2.17

Longo Analysis Report_Exhibit BB_04.28.2017

Longo MAS Project 14-1852 Below the Waist Application of Johnson's BP 9.2017

Longo Process Blanks for the Analysis of J&J's Products from the 60's to 90's for Asbestos

Longo TEM Analysis of Historical 1978 Johnson's BP Sample for Amphibole Asbestos 2.16.18

Longo Verification of Lee Poye's TEM Analysis of J&J's Historical Vermont Talc 11.5.18

Michael Crowley Expert Report Dated 11.12.18

Report of Results: MVA11730 Investigation of Italian Talc Samples for Asbestos 08.01.2017 RJLEE-001497

Thomas Dydek Brower Expert Report Dated 8.16.18 (corrected on 8.20.18)

Thomas Dydek Educational Report_FINAL (4-9-2018)

Thomas Dydek MDL Educational Report Dated 4.9.18

OTHER SOURCES:

American Cancer Society Ovarian Cancer Statistics

ATSDR Toxicological Profile for Asbestos

EPA Chemical Assessment Summary for Asbestos - 2017

EPA Guidelines for Carcinogen Risk Assessment - March 2005

EPA Health Assessment Document for Talc - 1992

Exhibit 1 - ATTORNEYS' EYES ONLY

Exhibit 2 - ATTORNEYS' EYES ONLY

Exhibit 3 - ATTORNEYS' EYES ONLY

FDA 4-1-2014 Response Letter to Epstein Denying Petition

Fitzgerald Analysis of J&J Baby Powder #1 and #2 Dated July 26, 2017

IARC Monograph 100C - Arsenic, Metals, Fibres, and Dusts - Excerpts

IARC Monograph 14 - Asbestos - 1977

IARC Monograph 2 - Some Inorganic and Organometallic Compounds - 1973

IARC Monograph 68 - Silica, Some Silicates, Coal Dust and Para-Aramid Fibrils - 1997

IARC Monograph 74 - Surgical Implants and Other Foreign Bodies - 1999

IARC Monograph 82 - Some Traditional Herbal Medicines, Some Mycotoxins, Naphthalene and Styrene - 2002

IARC Monograph 86 - Cobalt in Hard Minerals and Cobalt Sulfate, Gallium Arsenide, Indium Phosphide and Vanadium Pentoxide - 2006

IARC Monograph 87 - Inorganic and Organic Lead Compounds – 2006

IMERYS013188	J&J History
IMERYS045182	J&J S2s and BP Product Analysis - 1972
IMERYS045184	JNJ 000087928
IMERYS048311	JNJ 000088570
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IMERYS053387	JNJ000025132
IMERYS090653	JNJ000062359
IMERYS098115	JNJ000062436
IMERYS105215	JNJ000063608
IMERYS210136	JNJ000063951
IMERYS210729	JNJ000064544
IMERYS219720	JNJ000064762; JNJ000265171
IMERYS286445	JNJ000065264
IMERYS304036	JNJ000065601
IMERYS340454	JNJ000087710
IMERYS340798	JNJ000087716
IMERYS342524	JNJ000089413
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IMERYS422289	JNJ000237076
IMERYS 088907	JNJ000237379
IMERYS 284935	JNJ000239723
IMERYS137677-IMERYS137690	JNJ000239730
IMERYS209971	JNJ000245002
IMERYS241866	JNJ000246437
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IMERYS279968	JNJ000347962
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JNJ000025132	JNJ000526750
JNJ000026987	JNJ000886067
JNJ000046293	JNJAZ55_000000577
JNJ000245678	JNJAZ55_000000905
JNJ000245762	JNJAZ55_000004563
JNJ000251888	JNJAZ55_000008177
JNJ000260700	JNJL61_000014431
JNJ000261010	JNJMX68_000003728
JNJ000265536	JNJMX68_000012858
JNJ000279507	JNJMX68_000013019
JNJ000348778	JNJNL61_000079334

JNJ000404860

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Pltf_MISC_00000272 (JANSSEN-000001-19)

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NTP Technical Report on the Toxicology and Carcinogenesis Studies of Talc (CAS No.

14807-96-6)- 1993

NTP Toxicology and Carcinogenesis Studies of Talc in F344/N Rats and B6C3F Mice Report

No. 421

P-468

Read-the-Letter-from-the-FDA-on-Cosmetics

The Birth of Our Baby Products _ Kilmer House

WCD 002478 - Exhibit 32 Waldstreicher

Arch Carson, MD, PhD Legal Testimony, 2015-2018

Elaine Hale and Kenneth Dorsey parker, Jr. v. Centerpoint Energy Houston Electric, LLC; in the 55th District Court of Harris County, Texas.

2016 Harris County, TX for Plaintiff

Danny Henderson and Linda Henderson; Magdaleno Flores and Maria Flores; Shari Waldrop; and Bryan Thomas v. Magnablend, Inc., Nugreen Specialty, Inc., Nugreen Solutions, Inc., and Enviro Tech Inc.; in the 40th District Court of Ellis County, Texas.

2015 Ellis County, TX for Defendant

Edgar Guadalupe Solis v. Eastman Chemical Company, Texas Operations, Tradebe Environmental Services, Inc. d/b/a Tradebe Industrial Services LLC; in the 234th District Court of Harris County, Texas.

Harris County, TX for Defendant

Arch I. Carson, MD, PhD Professional Consultation Fee Schedule

Evidence-base research, report preparation, documentation, conference	\$450/hr
Interview, physical examination or medical testing of patients	450/hr
Review of documents	450/hr
Testimony at deposition or trial plus expenses	450/hr
Inspection, examination or sampling of physical evidence or sites	450/hr
Travel (Travel maximum \$4,000 per diem, plus expenses)	200/hr
Laboratory analyses/studies	at cost
Overhead and Supplies	at cost

Exhibit 19

Arch I. "Chip" Carson, M.D., Ph.D.

Page 1 IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF NEW JERSEY -----) IN RE JOHNSON & JOHNSON) TALCUM POWDER PRODUCTS MARKETING, SALES) MDL NO. PRACTICES, AND PRODUCTS) 16-2738 (FLW) (LHG) LIABILITY LITIGATION THIS DOCUMENT RELATES TO) ALL CASES Saturday, January 19, 2019

Videotaped Deposition of ARCH I. "CHIP" CARSON, M.D., Ph.D., held at the Marriott Houston Medical Center, 6580 Fannin Street, Houston, Texas, commencing at 9:02 a.m., on the above date, before Michael E. Miller, Fellow of the Academy of Professional Reporters, Certified Court Reporter, Registered Diplomate Reporter, Certified Realtime Reporter and Notary Public.

> GOLKOW LITIGATION SERVICES 877.370.DEPS | fax 917.591.5672 deps@golkow.com

Golkow Litigation Services - 1.877.370.DEPS

Arch I. "Chip" Carson, M.D., Ph.D.

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3	BY: P. LEIGH O'DELL, ESQUIRE leigh.odell@beasleyallen.com		2	APPEARANCES	2	
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5	Montgomery, Alabama 36103-4160 (334) 269-2343		5	EXAMINATION OF ARCI	H I. "CHIP" CARSO	ON, M.D., Ph.D.:
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23 24	Defendants		23			
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3	Materials Reviewed by Dr. Carson	3	THE VIDEOGRAPHER: We are now
4		4	on the record. My name is Doug
_	Exhibit 16 1979 Chappell et al 130	5	Overstreet. I'm the videographer for
5 6	Publication Exhibit 17 2011 Reid et al Publication 159	6	Golkow Litigation Services. Today is
7	Exhibit 18 2011 Camargo et al 163	7	January 19th, 2019. The time is
8	Publication	8	9:02 a.m.
0	Exhibit 19 2013 Terry et al 192	9	This video deposition is being
9	Publication	10	held in Houston, Texas in the matter
10	Exhibit 20 2016 Cramer et al 195 Publication	11	of Talcum Powder Litigation MDL
11	1 donedion	12	No. 2738.
1.0	Exhibit 21 IARC Classification Groups 225	13	The deponent is Dr. Chip
12 13	Document Exhibit 22 2017 Berge et al 243	14	Carson.
	Publication	15	Will counsel please identify
14	Eultibit 22 2007 Languagh et al. 247	16	themselves for the record.
15	Exhibit 23 2007 Langseth et al 247 Publication		
16	Exhibit 24 2016 Schildkraut et al 271	17	MS. O'DELL: Leigh O'Dell,
17	Publication	18	Beasley Allen, for the plaintiffs.
1 '	Exhibit 25 Excerpt from IARC 289	19	DR. THOMPSON: Margaret
18	Monograph 93	20	Thompson, Beasley Allen, for the
19 20		21	plaintiffs.
21		22	MS. KLEVORN: Amanda Klevorn,
22		23	Burns Charest, for the plaintiffs.
23 24		24	MR. ZELLERS: Michael Zellers
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	REFERENCED EXHIBITS NUMBER PAGE Exhibit	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	for the Johnson & Johnson defendants. MS. McBETH: Katherine McBeth, Drinker Biddle & Reath, for the Johnson & Johnson defendants as well. MS. BOCKUS: Jane Bockus for Imerys. MR. DONATH: Jonathan Donath from Coughlin Duffy for Imerys. MS. APPEL: Renée Appel from Seyfarth Shaw for Personal Care Products. MS. TINSLEY: Caroline Tinsley, Tucker Ellis, for PTI Union, LLC and PTI Royston, LLC. THE VIDEOGRAPHER: The court reporter today is Mr. Mike Miller, and he will now swear in the witness.
17 18 19 20 21 22 23 24		18 19 20 21 22 23 24	ARCH I. "CHIP" CARSON, M.D., Ph.D., having been duly sworn, testified as follows: EXAMINATION BY MR. ZELLERS: Q. Can you state your name, please.

3 (Pages 6 to 9)

	Page 10		Page 12
1	A. Arch Carson.	1	BY MR. ZELLERS:
2	Q. You are a physician; is that	2	Q. As best we can, let me finish
3	right?	3	my question before you start to give your
4	A. I am.	4	answer. I'll do the same and allow you to
5	Q. A medical toxicologist?	5	finish your answer before I ask you another
6	A. Yes.	6	question so our court reporter can take down
7	Q. We are here today to take your	7	what each of us say.
8	deposition in the talc MDL litigation	8	Can you do that?
9	proceedings; is that right?	9	A. Yes.
10	A. As far as I know, yes.	10	Q. In response to the notice of
11	Q. You are an expert witness for	11	deposition, which we've marked as Exhibit 1,
12	the plaintiffs in that litigation; is that	12	have you brought with you certain documents
13	right?	13	here today?
14	A. Yes.	14	A. I have a collection of
15	Q. Did you receive a notice of	15	documents that in part respond to these
16	deposition, which we'll mark as Exhibit 1, to	16	requests, yes.
17	appear here today?	17	Q. Do you have any documents in
18	(Carson Deposition Exhibit 1	18	your possession that are responsive to the
19	marked.)	19	notice of deposition, Exhibit 1, that you
20	A. Yes, I received a copy of this	20	have not brought here today?
21	document.	21	A. I would have to go through
22	MS. O'DELL: And, Michael, just	22	these things one by one, but
23	for the record, we just reassert all	23	Q. You didn't do that before we
24	our previously served objections to	24	came here today?
	Page 11		Page 13
1	the notice.	1	A. I did, but the plaintiffs'
2	MR. ZELLERS: Thank you.	2	attorneys
3	BY MR. ZELLERS:	3	MS. O'DELL: Let me just stop
4	Q. You have given deposition	4	you, Dr. Carson, just because
5	testimony in the past; is that right?	5	discussing what we've discussed is not
6	A. I have.	6	within the purview of this deposition.
7	Q. On how many occasions?	7	That's privileged. Let me just say
8	A. Probably 30, 35.	8	THE WITNESS: All right.
9	Q. You are familiar with the	9	MS. O'DELL: Dr. Carson, in
10	procedures we're going to follow today?	10	response to the notice, has brought
11	A. More or less, I think.	11	with him copies of the cited materials
12	Q. If at any time I ask you a	12	in his report, and that's in the
13	question and you don't understand it, tell me	13	binder that is to his left.
14	you don't understand it and I'll repeat it or	14	He's brought with him copies of
15	rephrase it to try to make it clear to you.	15	certain documents that were listed on
16	Can you do that?	16	his materials considered list. He
17	A. Yes.	17	doesn't have a physical copy of
	Q. If you answer a question that I	18	everything on his materials considered
18		19	list.
19	ask or that any of the counsel ask, we're		
19 20	going to assume that you understood it; is	20	I brought today a thumb drive
19 20 21	going to assume that you understood it; is that fair?	20 21	that has a copy of all the items on
19 20 21 22	going to assume that you understood it; is that fair? MS. O'DELL: Object to form.	20 21 22	that has a copy of all the items on his materials considered list. If you
19 20 21	going to assume that you understood it; is that fair?	20 21	that has a copy of all the items on

4 (Pages 10 to 13)

	Page 14		Page 16
1	And then in addition, he has	1	Q. I'll ask you about the
2	brought some additional materials that	2	attachments in a moment.
3	he has reviewed since the service of	3	Does this report,
4	his report.	4	Deposition Exhibit 2, contain all of the
5	The only other item, as I	5	opinions that you intend to offer at any
6	recall, on the notice of deposition	6	trial or hearing of this matter?
7	request for documents that has not	7	A. In general, it contains all of
8	been brought to the deposition is	8	my opinions. I expect to expand on those
9	copies of invoices and Dr. Carson has	9	opinions possibly in this deposition or in
10	not sent us an invoice. That's why we	10	the future.
11	don't have a copy.	11	Q. Today's my opportunity to ask
12	So to try to short-circuit	12	you what your opinions are in this matter.
13	this, just to make sure since we made	13	As of today, are the opinions
14	decisions about what's produced and	14	that you expressed to us set forth at any
15	what's not, I'll just say all that for	15	trial or hearing in this matter, are they
16	the record. And if you'd like that,	16	contained in your report, Exhibit 2?
17	you're welcome to it.	17	A. I have seen information that
18	BY MR. ZELLERS:	18	has become available recently that I did not
19	Q. Dr. Carson, you heard	19	have at that time this report was finalized,
20	Ms. O'Dell describe what you brought here	20	and I have modified my opinions very slightly
21	today. Is all of that accurate?	21	as a result of that information.
22	A. It is.	22	Q. How have you modified your
23	Q. Are you aware of there being	23	opinions?
24	any documents or materials that are	24	A. My opinions have essentially
21	any documents of materials that are	21	A. My opinions have essentially
	Page 15		Page 17
			rage 17
1	responsive to the deposition notice that you	1	been strengthened as they relate to the
1 2	responsive to the deposition notice that you have not brought with you here today?	1 2	
		l	been strengthened as they relate to the
2	have not brought with you here today?	2	been strengthened as they relate to the causation question between perineal talcum
2	have not brought with you here today? A. No.	2 3	been strengthened as they relate to the causation question between perineal talcum powder use and the occurrence of ovarian
2 3 4	have not brought with you here today? A. No. Q. I'm trying to understand what	2 3 4	been strengthened as they relate to the causation question between perineal talcum powder use and the occurrence of ovarian cancers.
2 3 4 5	have not brought with you here today? A. No. Q. I'm trying to understand what counsel for plaintiffs, Ms. O'Dell, has said,	2 3 4 5	been strengthened as they relate to the causation question between perineal talcum powder use and the occurrence of ovarian cancers. Q. Other than you believing that
2 3 4 5 6	have not brought with you here today? A. No. Q. I'm trying to understand what counsel for plaintiffs, Ms. O'Dell, has said, so let me ask you some questions.	2 3 4 5 6	been strengthened as they relate to the causation question between perineal talcum powder use and the occurrence of ovarian cancers. Q. Other than you believing that your opinions are strengthened with respect
2 3 4 5 6 7	have not brought with you here today? A. No. Q. I'm trying to understand what counsel for plaintiffs, Ms. O'Dell, has said, so let me ask you some questions. You have brought with you today in a binder some of the cited materials in your report; is that right?	2 3 4 5 6 7	been strengthened as they relate to the causation question between perineal talcum powder use and the occurrence of ovarian cancers. Q. Other than you believing that your opinions are strengthened with respect to the association between perineal talcum
2 3 4 5 6 7 8	have not brought with you here today? A. No. Q. I'm trying to understand what counsel for plaintiffs, Ms. O'Dell, has said, so let me ask you some questions. You have brought with you today in a binder some of the cited materials in	2 3 4 5 6 7 8	been strengthened as they relate to the causation question between perineal talcum powder use and the occurrence of ovarian cancers. Q. Other than you believing that your opinions are strengthened with respect to the association between perineal talcum powder use and ovarian cancer, have your
2 3 4 5 6 7 8 9 10	have not brought with you here today? A. No. Q. I'm trying to understand what counsel for plaintiffs, Ms. O'Dell, has said, so let me ask you some questions. You have brought with you today in a binder some of the cited materials in your report; is that right? A. Yes. This is intended to be a complete set of the cited references, with	2 3 4 5 6 7 8 9 10	been strengthened as they relate to the causation question between perineal talcum powder use and the occurrence of ovarian cancers. Q. Other than you believing that your opinions are strengthened with respect to the association between perineal talcum powder use and ovarian cancer, have your opinions changed at all since you prepared your report, Exhibit 2? A. No.
2 3 4 5 6 7 8 9 10 11	have not brought with you here today? A. No. Q. I'm trying to understand what counsel for plaintiffs, Ms. O'Dell, has said, so let me ask you some questions. You have brought with you today in a binder some of the cited materials in your report; is that right? A. Yes. This is intended to be a complete set of the cited references, with one exception.	2 3 4 5 6 7 8 9 10 11	been strengthened as they relate to the causation question between perineal talcum powder use and the occurrence of ovarian cancers. Q. Other than you believing that your opinions are strengthened with respect to the association between perineal talcum powder use and ovarian cancer, have your opinions changed at all since you prepared your report, Exhibit 2? A. No. Q. Are there any new or additional
2 3 4 5 6 7 8 9 10	have not brought with you here today? A. No. Q. I'm trying to understand what counsel for plaintiffs, Ms. O'Dell, has said, so let me ask you some questions. You have brought with you today in a binder some of the cited materials in your report; is that right? A. Yes. This is intended to be a complete set of the cited references, with one exception. Q. When you say cited	2 3 4 5 6 7 8 9 10	been strengthened as they relate to the causation question between perineal talcum powder use and the occurrence of ovarian cancers. Q. Other than you believing that your opinions are strengthened with respect to the association between perineal talcum powder use and ovarian cancer, have your opinions changed at all since you prepared your report, Exhibit 2? A. No. Q. Are there any new or additional opinions as of today that you expect to
2 3 4 5 6 7 8 9 10 11	have not brought with you here today? A. No. Q. I'm trying to understand what counsel for plaintiffs, Ms. O'Dell, has said, so let me ask you some questions. You have brought with you today in a binder some of the cited materials in your report; is that right? A. Yes. This is intended to be a complete set of the cited references, with one exception.	2 3 4 5 6 7 8 9 10 11	been strengthened as they relate to the causation question between perineal talcum powder use and the occurrence of ovarian cancers. Q. Other than you believing that your opinions are strengthened with respect to the association between perineal talcum powder use and ovarian cancer, have your opinions changed at all since you prepared your report, Exhibit 2? A. No. Q. Are there any new or additional opinions as of today that you expect to testify to at trial or any hearing of this
2 3 4 5 6 7 8 9 10 11 12 13 14 15	have not brought with you here today? A. No. Q. I'm trying to understand what counsel for plaintiffs, Ms. O'Dell, has said, so let me ask you some questions. You have brought with you today in a binder some of the cited materials in your report; is that right? A. Yes. This is intended to be a complete set of the cited references, with one exception. Q. When you say cited	2 3 4 5 6 7 8 9 10 11 12 13	been strengthened as they relate to the causation question between perineal talcum powder use and the occurrence of ovarian cancers. Q. Other than you believing that your opinions are strengthened with respect to the association between perineal talcum powder use and ovarian cancer, have your opinions changed at all since you prepared your report, Exhibit 2? A. No. Q. Are there any new or additional opinions as of today that you expect to testify to at trial or any hearing of this matter other than your report, Exhibit 2, and
2 3 4 5 6 7 8 9 10 11 12 13 14	have not brought with you here today? A. No. Q. I'm trying to understand what counsel for plaintiffs, Ms. O'Dell, has said, so let me ask you some questions. You have brought with you today in a binder some of the cited materials in your report; is that right? A. Yes. This is intended to be a complete set of the cited references, with one exception. Q. When you say cited references A. From my report. Q. Your expert report, we will	2 3 4 5 6 7 8 9 10 11 12 13	been strengthened as they relate to the causation question between perineal talcum powder use and the occurrence of ovarian cancers. Q. Other than you believing that your opinions are strengthened with respect to the association between perineal talcum powder use and ovarian cancer, have your opinions changed at all since you prepared your report, Exhibit 2? A. No. Q. Are there any new or additional opinions as of today that you expect to testify to at trial or any hearing of this matter other than your report, Exhibit 2, and as you have qualified that report by stating
2 3 4 5 6 7 8 9 10 11 12 13 14 15	have not brought with you here today? A. No. Q. I'm trying to understand what counsel for plaintiffs, Ms. O'Dell, has said, so let me ask you some questions. You have brought with you today in a binder some of the cited materials in your report; is that right? A. Yes. This is intended to be a complete set of the cited references, with one exception. Q. When you say cited references A. From my report.	2 3 4 5 6 7 8 9 10 11 12 13 14 15	been strengthened as they relate to the causation question between perineal talcum powder use and the occurrence of ovarian cancers. Q. Other than you believing that your opinions are strengthened with respect to the association between perineal talcum powder use and ovarian cancer, have your opinions changed at all since you prepared your report, Exhibit 2? A. No. Q. Are there any new or additional opinions as of today that you expect to testify to at trial or any hearing of this matter other than your report, Exhibit 2, and
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	have not brought with you here today? A. No. Q. I'm trying to understand what counsel for plaintiffs, Ms. O'Dell, has said, so let me ask you some questions. You have brought with you today in a binder some of the cited materials in your report; is that right? A. Yes. This is intended to be a complete set of the cited references, with one exception. Q. When you say cited references A. From my report. Q. Your expert report, we will	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	been strengthened as they relate to the causation question between perineal talcum powder use and the occurrence of ovarian cancers. Q. Other than you believing that your opinions are strengthened with respect to the association between perineal talcum powder use and ovarian cancer, have your opinions changed at all since you prepared your report, Exhibit 2? A. No. Q. Are there any new or additional opinions as of today that you expect to testify to at trial or any hearing of this matter other than your report, Exhibit 2, and as you have qualified that report by stating
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	have not brought with you here today? A. No. Q. I'm trying to understand what counsel for plaintiffs, Ms. O'Dell, has said, so let me ask you some questions. You have brought with you today in a binder some of the cited materials in your report; is that right? A. Yes. This is intended to be a complete set of the cited references, with one exception. Q. When you say cited references A. From my report. Q. Your expert report, we will mark as Exhibit 2.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	been strengthened as they relate to the causation question between perineal talcum powder use and the occurrence of ovarian cancers. Q. Other than you believing that your opinions are strengthened with respect to the association between perineal talcum powder use and ovarian cancer, have your opinions changed at all since you prepared your report, Exhibit 2? A. No. Q. Are there any new or additional opinions as of today that you expect to testify to at trial or any hearing of this matter other than your report, Exhibit 2, and as you have qualified that report by stating that your opinions on association are
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	have not brought with you here today? A. No. Q. I'm trying to understand what counsel for plaintiffs, Ms. O'Dell, has said, so let me ask you some questions. You have brought with you today in a binder some of the cited materials in your report; is that right? A. Yes. This is intended to be a complete set of the cited references, with one exception. Q. When you say cited references A. From my report. Q. Your expert report, we will mark as Exhibit 2. (Carson Deposition Exhibit 2	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	been strengthened as they relate to the causation question between perineal talcum powder use and the occurrence of ovarian cancers. Q. Other than you believing that your opinions are strengthened with respect to the association between perineal talcum powder use and ovarian cancer, have your opinions changed at all since you prepared your report, Exhibit 2? A. No. Q. Are there any new or additional opinions as of today that you expect to testify to at trial or any hearing of this matter other than your report, Exhibit 2, and as you have qualified that report by stating that your opinions on association are stronger today?
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	have not brought with you here today? A. No. Q. I'm trying to understand what counsel for plaintiffs, Ms. O'Dell, has said, so let me ask you some questions. You have brought with you today in a binder some of the cited materials in your report; is that right? A. Yes. This is intended to be a complete set of the cited references, with one exception. Q. When you say cited references A. From my report. Q. Your expert report, we will mark as Exhibit 2. (Carson Deposition Exhibit 2 marked.)	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	been strengthened as they relate to the causation question between perineal talcum powder use and the occurrence of ovarian cancers. Q. Other than you believing that your opinions are strengthened with respect to the association between perineal talcum powder use and ovarian cancer, have your opinions changed at all since you prepared your report, Exhibit 2? A. No. Q. Are there any new or additional opinions as of today that you expect to testify to at trial or any hearing of this matter other than your report, Exhibit 2, and as you have qualified that report by stating that your opinions on association are stronger today? A. No.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	have not brought with you here today? A. No. Q. I'm trying to understand what counsel for plaintiffs, Ms. O'Dell, has said, so let me ask you some questions. You have brought with you today in a binder some of the cited materials in your report; is that right? A. Yes. This is intended to be a complete set of the cited references, with one exception. Q. When you say cited references A. From my report. Q. Your expert report, we will mark as Exhibit 2. (Carson Deposition Exhibit 2 marked.) BY MR. ZELLERS:	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	been strengthened as they relate to the causation question between perineal talcum powder use and the occurrence of ovarian cancers. Q. Other than you believing that your opinions are strengthened with respect to the association between perineal talcum powder use and ovarian cancer, have your opinions changed at all since you prepared your report, Exhibit 2? A. No. Q. Are there any new or additional opinions as of today that you expect to testify to at trial or any hearing of this matter other than your report, Exhibit 2, and as you have qualified that report by stating that your opinions on association are stronger today? A. No. MS. O'DELL: Object to the
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	have not brought with you here today? A. No. Q. I'm trying to understand what counsel for plaintiffs, Ms. O'Dell, has said, so let me ask you some questions. You have brought with you today in a binder some of the cited materials in your report; is that right? A. Yes. This is intended to be a complete set of the cited references, with one exception. Q. When you say cited references A. From my report. Q. Your expert report, we will mark as Exhibit 2. (Carson Deposition Exhibit 2 marked.) BY MR. ZELLERS: Q. Is Deposition Exhibit 2 your	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	been strengthened as they relate to the causation question between perineal talcum powder use and the occurrence of ovarian cancers. Q. Other than you believing that your opinions are strengthened with respect to the association between perineal talcum powder use and ovarian cancer, have your opinions changed at all since you prepared your report, Exhibit 2? A. No. Q. Are there any new or additional opinions as of today that you expect to testify to at trial or any hearing of this matter other than your report, Exhibit 2, and as you have qualified that report by stating that your opinions on association are stronger today? A. No. MS. O'DELL: Object to the form.

5 (Pages 14 to 17)

	Page 18		Page 20
1	Do you see that?	1	I produced a report that I
2	A. Yes.	2	thought was responsive to the question that
3	Q. What are the references? What	3	was given to me by the plaintiffs' attorneys,
4	do they relate to? And by that, I mean	4	and within that report I felt it necessary to
5	I'm just trying to understand what this list	5	cite specific key references that contributed
6	is.	6	to items in that report.
7	A. This is a list of references	7	BY MR. ZELLERS:
8	from which I gleaned information that were	8	Q. And those are
9	important to my forming opinions regarding	9	MS. O'DELL: Excuse me, sir.
10	the question that was given to me, and they	10	Are you finished, Dr. Carson?
11	contribute to pieces of the report in various	11	THE WITNESS: Yes.
12	ways.	12	MS. O'DELL: Okay. Sorry.
13	They don't represent a complete	13	BY MR. ZELLERS:
14	review that I made in preparing my report,	14	Q. Those are the items that you've
15		15	
	but all are important in some way in terms of	16	listed under References; is that right?
16	coming to my conclusions.	1	A. Yes.
17	Q. Are the references that you	17	Q. Literature are other materials
18	list in your report from page 11 up and	18	that you have reviewed but didn't rise to the
19	through page 16, are those the materials that	19	level of you citing them as a reference for
20	you are relying on in terms of your opinions	20	your report, correct?
21	that you're expressing in your report?	21	A. That is correct, but they do
22	MS. O'DELL: Objection to form.	22	contribute information that I utilize in
23	A. Yes.	23	terms of the whole to formulate my opinions.
24	///	24	Q. Let me mark several of the
	Page 19		Page 21
1	BY MR. ZELLERS:	1	attachments to your report as separate
2	Q. What, then, is the difference	2	exhibits.
3	between the references to your report and	3	(Carson Deposition Exhibit 3
4	Exhibit B, which has a caption, Literature?	4	marked.)
5	A. The Exhibit B represents a	5	BY MR. ZELLERS:
6	larger set of documents, including scientific	6	Q. Exhibit 3 is your curriculum
7	literature, technical reports, and so forth	7	vitae that was attached to your report; is
8	that I reviewed in preparation of my report	8	that right?
9	and the formation of my opinions; but they	9	A. Yes.
10	did not contain information that I felt	10	(Carson Deposition Exhibit 4
11	necessary to cite in my report.	11	marked.)
		12	BY MR. ZELLERS:
12	O THE INFRAINTE MAI VOILCHE TO		BI MIK. EEEEERS.
12 13	•	13	O. Exhibit 4 is a conv of your
13	as Appendix B of your report are materials	13 14	Q. Exhibit 4 is a copy of your
13 14	as Appendix B of your report are materials that you reviewed but are not the materials	14	literature list that we just discussed that
13 14 15	as Appendix B of your report are materials that you reviewed but are not the materials that you're specifically relying on. The	14 15	literature list that we just discussed that is in your report; is that right?
13 14 15 16	as Appendix B of your report are materials that you reviewed but are not the materials that you're specifically relying on. The materials that you're specifically relying on	14 15 16	literature list that we just discussed that is in your report; is that right? A. Yes.
13 14 15 16 17	as Appendix B of your report are materials that you reviewed but are not the materials that you're specifically relying on. The materials that you're specifically relying on are set forth in your references list; is	14 15 16 17	literature list that we just discussed that is in your report; is that right? A. Yes. MS. O'DELL: Thank you.
13 14 15 16 17 18	as Appendix B of your report are materials that you reviewed but are not the materials that you're specifically relying on. The materials that you're specifically relying on are set forth in your references list; is that right?	14 15 16 17 18	literature list that we just discussed that is in your report; is that right? A. Yes. MS. O'DELL: Thank you. BY MR. ZELLERS:
13 14 15 16 17 18 19	as Appendix B of your report are materials that you reviewed but are not the materials that you're specifically relying on. The materials that you're specifically relying on are set forth in your references list; is that right? MS. O'DELL: Excuse me. Object	14 15 16 17 18 19	literature list that we just discussed that is in your report; is that right? A. Yes. MS. O'DELL: Thank you. BY MR. ZELLERS: Q. The one difference with
13 14 15 16 17 18 19 20	as Appendix B of your report are materials that you reviewed but are not the materials that you're specifically relying on. The materials that you're specifically relying on are set forth in your references list; is that right? MS. O'DELL: Excuse me. Object to the form, misstates his testimony.	14 15 16 17 18 19 20	literature list that we just discussed that is in your report; is that right? A. Yes. MS. O'DELL: Thank you. BY MR. ZELLERS: Q. The one difference with Exhibit 4, your literature list that's
13 14 15 16 17 18 19 20 21	as Appendix B of your report are materials that you reviewed but are not the materials that you're specifically relying on. The materials that you're specifically relying on are set forth in your references list; is that right? MS. O'DELL: Excuse me. Object to the form, misstates his testimony. A. My opinions are based on my	14 15 16 17 18 19 20 21	literature list that we just discussed that is in your report; is that right? A. Yes. MS. O'DELL: Thank you. BY MR. ZELLERS: Q. The one difference with Exhibit 4, your literature list that's attached to your report as Appendix B is not
13 14 15 16 17 18 19 20 21 22	as Appendix B of your report are materials that you reviewed but are not the materials that you're specifically relying on. The materials that you're specifically relying on are set forth in your references list; is that right? MS. O'DELL: Excuse me. Object to the form, misstates his testimony. A. My opinions are based on my total review of the literature as well as my	14 15 16 17 18 19 20 21	literature list that we just discussed that is in your report; is that right? A. Yes. MS. O'DELL: Thank you. BY MR. ZELLERS: Q. The one difference with Exhibit 4, your literature list that's attached to your report as Appendix B is not numbered. I've gone ahead and numbered the
13 14 15 16 17 18 19 20 21	as Appendix B of your report are materials that you reviewed but are not the materials that you're specifically relying on. The materials that you're specifically relying on are set forth in your references list; is that right? MS. O'DELL: Excuse me. Object to the form, misstates his testimony. A. My opinions are based on my	14 15 16 17 18 19 20 21	literature list that we just discussed that is in your report; is that right? A. Yes. MS. O'DELL: Thank you. BY MR. ZELLERS: Q. The one difference with Exhibit 4, your literature list that's attached to your report as Appendix B is not

6 (Pages 18 to 21)

			·
	Page 22		Page 24
1	Today, when I refer to	1	binder of materials; is that right?
2	products, tale products, baby powder or	2	A. Yes.
3	Shower to Shower, I'm referring to the baby	3	Q. The binder of materials, did
4	powder product manufactured by Johnson &	4	you prepare that, or was it prepared for you?
5	Johnson Consumer Products Inc. and the Shower	5	A. Well, I uploaded documents to a
6	to Shower product formerly manufactured by	6	share file, and the plaintiffs' attorneys
7	Johnson & Johnson Consumer Products Inc.	7	were kind enough to print those for me and
8	Do you understand that?	8	assemble them in the binder.
9	A. Yes.	9	Q. In addition, you have brought
10	Q. Is your report, Exhibit 2,	10	with you a stack of eight or so additional
11	accurate?	11	references that you have on the table in
12	A. I believe so.	12	front of you; is that right?
13	Q. Do you believe it's complete?	13	A. Yes.
14	A. In terms of its focus, yes.	14	Q. Are those materials that were
15	Q. What do you mean in terms of	15	cited either as references in your report or
16	its focus?	16	in the literature section of your report?
17	A. It covers specific aspects of a	17	
18	larger question, and regarding those specific	1	
19		18	one or the other of those lists.
	aspects, I believe it is complete.	19	Q. Your testimony under oath is
20	Q. It covers the aspects of the	20	that all of the additional materials you
21	question that you intend to offer opinions	21	brought here today are referred to either in
22	on, correct?	22	your reference list, which is begins at
23	A. That is correct.	23	page 11 of your report, or your literature
24	Q. What is the question that was	24	list, which we've marked as Exhibit 4 and is
	Page 23		Page 25
1	given to you by counsel for plaintiffs in	1	Exhibit B to your report; is that right?
2	this litigation?	2	MS. O'DELL: Objection to the
3	A. The question is do the does	3	form.
4	the habitual use of talcum powder products	4	Go ahead.
5	cause ovarian cancer.	5	A. There are a couple of new
6	Q. Were you given any other	6	articles here that were not available at the
7	questions to answer or opine on in this	7	time that I submitted my report, and I
8	litigation?	8	believe the literature list was also created.
9	A. Not specifically.	9	BY MR. ZELLERS:
10	Q. What do you understand habitual	10	Q. Were those new materials
11	use of talcum powder to refer to?	11	provided to you by plaintiffs' counsel or are
12	A. It means routine use, periodic	12	those materials that you did some type of
13	use.	13	literature search and found?
14	Q. Over any period of time?	14	A. One of them was provided to me
15	A. Over an extended period of	15	by plaintiffs' counsel, but I was aware that
16	time.	16	it was coming. And actually, two of them
17	Q. What is an extended period of	17	were provided by plaintiffs' counsel.
18	time?	18	Q. All right. The two additional
19	A. Months or years.	19	documents that were provided to you by
20	Q. Any other definition that you	20	plaintiffs' counsel, can you show those to
21	have of habitual use?	21	me?
22	A. No.	22	A. Okay. One is the Longo report.
23	Q. Today, in response to the	23	Q. We will mark as
23 24	notice of deposition, you did bring the	24	Deposition Exhibit 5 the Longo report dated
∠ ±	nonce of deposition, you did offing the	47	Deposition Exhibit 5 the Longo report dated

7 (Pages 22 to 25)

	Page 26		Page 28
1	January 15th of 2009 [sic].	1	Ph.D.; is that right?
2	(Carson Deposition Exhibit 5	2	A. Yes.
3	marked.)	3	Q. What additional articles have
4	A. The other is the recent	4	you brought here with you today separate and
5	Fletcher, et al article.	5	apart from your binder of materials?
6	(Carson Deposition Exhibit 6	6	A. There's a copy of the IARC
7	marked.)	7	monographs preamble.
8	BY MR. ZELLERS:	8	Q. For what purpose did you bring
9	O. The Fletcher article dated	9	that article?
10	January 3rd of 2019 we'll mark as Exhibit 6.	10	A. This discusses the general
11	This is an article from Reproductive	11	process that IARC uses in approaching a
12	Sciences; is that right?	12	putative carcinogenic material.
13	A. Yes. And I actually have a	13	Q. That has previously been marked
14	third.	14	as Plaintiff Exhibit P-346 in another
15	Q. All right. You have a third	15	proceeding; is that right?
16	article that was provided to you by	16	A. I don't know.
17	plaintiffs' counsel?	17	Q. Well, the document we're
18	A. Yes.	18	looking at has that exhibit sticker on it; is
19	(Carson Deposition Exhibit 7	19	that right?
20	marked.)	20	A. It does.
21	BY MR. ZELLERS:	21	Q. What else have you brought here
22	O. Let's mark that as	22	with you today?
23	Deposition Exhibit 7. Can you tell us what	23	A. This is an article from
24	article that is?	24	The Lancet from 1952 titled Value of Modified
	article that is:		The Edited from 1932 titled value of Modified
	Page 27		Page 29
1	A. This is a meta-analysis.	1	Starch as a Substitute for Talc, and the
2	It's the title is Systematic Review and	2	first author is J.D.P. Graham.
3	Meta-Analysis of the Association Between	3	Q. Why did you bring that article?
4	Perineal Use of Talc and Risk of Ovarian		
	i cimear ese of fale and resk of evarian	4	A. This is an older article that
5	Cancer. The lead author is Mohamed Taher.	5	A. This is an older article that discusses the suitability of substituting
5 6			
	Cancer. The lead author is Mohamed Taher.	5	discusses the suitability of substituting
6	Cancer. The lead author is Mohamed Taher. Q. The Taher paper we have marked	5 6	discusses the suitability of substituting cornstarch materials for talc due to
6 7	Cancer. The lead author is Mohamed Taher. Q. The Taher paper we have marked as Exhibit 7; is that right?	5 6 7	discusses the suitability of substituting cornstarch materials for talc due to perceived issues with talc.
6 7 8	Cancer. The lead author is Mohamed Taher. Q. The Taher paper we have marked as Exhibit 7; is that right? A. Yes.	5 6 7 8	discusses the suitability of substituting cornstarch materials for talc due to perceived issues with talc. Q. Is this an article that you had
6 7 8 9	Cancer. The lead author is Mohamed Taher. Q. The Taher paper we have marked as Exhibit 7; is that right? A. Yes. Q. This is something that you were	5 6 7 8 9	discusses the suitability of substituting cornstarch materials for talc due to perceived issues with talc. Q. Is this an article that you had cited previously, either in your references
6 7 8 9 10	Cancer. The lead author is Mohamed Taher. Q. The Taher paper we have marked as Exhibit 7; is that right? A. Yes. Q. This is something that you were provided by plaintiffs' counsel; is that	5 6 7 8 9	discusses the suitability of substituting cornstarch materials for talc due to perceived issues with talc. Q. Is this an article that you had cited previously, either in your references or your list of literature?
6 7 8 9 10 11	Cancer. The lead author is Mohamed Taher. Q. The Taher paper we have marked as Exhibit 7; is that right? A. Yes. Q. This is something that you were provided by plaintiffs' counsel; is that right? A. Yes. Q. Exhibit 6, Reproductive	5 6 7 8 9 10 11	discusses the suitability of substituting cornstarch materials for talc due to perceived issues with talc. Q. Is this an article that you had cited previously, either in your references or your list of literature? A. I did not cite it in my report.
6 7 8 9 10 11 12	Cancer. The lead author is Mohamed Taher. Q. The Taher paper we have marked as Exhibit 7; is that right? A. Yes. Q. This is something that you were provided by plaintiffs' counsel; is that right? A. Yes. Q. Exhibit 6, Reproductive Sciences, are you familiar with that journal?	5 6 7 8 9 10 11	discusses the suitability of substituting cornstarch materials for talc due to perceived issues with talc. Q. Is this an article that you had cited previously, either in your references or your list of literature? A. I did not cite it in my report. I don't know I don't recall if it's in the
6 7 8 9 10 11 12 13	Cancer. The lead author is Mohamed Taher. Q. The Taher paper we have marked as Exhibit 7; is that right? A. Yes. Q. This is something that you were provided by plaintiffs' counsel; is that right? A. Yes. Q. Exhibit 6, Reproductive	5 6 7 8 9 10 11 12 13	discusses the suitability of substituting cornstarch materials for talc due to perceived issues with talc. Q. Is this an article that you had cited previously, either in your references or your list of literature? A. I did not cite it in my report. I don't know I don't recall if it's in the literature list or not.
6 7 8 9 10 11 12 13	Cancer. The lead author is Mohamed Taher. Q. The Taher paper we have marked as Exhibit 7; is that right? A. Yes. Q. This is something that you were provided by plaintiffs' counsel; is that right? A. Yes. Q. Exhibit 6, Reproductive Sciences, are you familiar with that journal? A. I'm aware that it exists. Q. Do you review that journal on a	5 6 7 8 9 10 11 12 13 14	discusses the suitability of substituting cornstarch materials for talc due to perceived issues with talc. Q. Is this an article that you had cited previously, either in your references or your list of literature? A. I did not cite it in my report. I don't know I don't recall if it's in the literature list or not. (Carson Deposition Exhibit 8
6 7 8 9 10 11 12 13 14	Cancer. The lead author is Mohamed Taher. Q. The Taher paper we have marked as Exhibit 7; is that right? A. Yes. Q. This is something that you were provided by plaintiffs' counsel; is that right? A. Yes. Q. Exhibit 6, Reproductive Sciences, are you familiar with that journal? A. I'm aware that it exists.	5 6 7 8 9 10 11 12 13 14 15	discusses the suitability of substituting cornstarch materials for talc due to perceived issues with talc. Q. Is this an article that you had cited previously, either in your references or your list of literature? A. I did not cite it in my report. I don't know I don't recall if it's in the literature list or not. (Carson Deposition Exhibit 8 marked.)
6 7 8 9 10 11 12 13 14 15	Cancer. The lead author is Mohamed Taher. Q. The Taher paper we have marked as Exhibit 7; is that right? A. Yes. Q. This is something that you were provided by plaintiffs' counsel; is that right? A. Yes. Q. Exhibit 6, Reproductive Sciences, are you familiar with that journal? A. I'm aware that it exists. Q. Do you review that journal on a	5 6 7 8 9 10 11 12 13 14 15	discusses the suitability of substituting cornstarch materials for talc due to perceived issues with talc. Q. Is this an article that you had cited previously, either in your references or your list of literature? A. I did not cite it in my report. I don't know I don't recall if it's in the literature list or not. (Carson Deposition Exhibit 8 marked.) BY MR. ZELLERS:
6 7 8 9 10 11 12 13 14 15 16	Cancer. The lead author is Mohamed Taher. Q. The Taher paper we have marked as Exhibit 7; is that right? A. Yes. Q. This is something that you were provided by plaintiffs' counsel; is that right? A. Yes. Q. Exhibit 6, Reproductive Sciences, are you familiar with that journal? A. I'm aware that it exists. Q. Do you review that journal on a regular basis as a part of your clinical and	5 6 7 8 9 10 11 12 13 14 15 16	discusses the suitability of substituting cornstarch materials for talc due to perceived issues with talc. Q. Is this an article that you had cited previously, either in your references or your list of literature? A. I did not cite it in my report. I don't know I don't recall if it's in the literature list or not. (Carson Deposition Exhibit 8 marked.) BY MR. ZELLERS: Q. Why did you decide to bring
6 7 8 9 10 11 12 13 14 15 16 17	Cancer. The lead author is Mohamed Taher. Q. The Taher paper we have marked as Exhibit 7; is that right? A. Yes. Q. This is something that you were provided by plaintiffs' counsel; is that right? A. Yes. Q. Exhibit 6, Reproductive Sciences, are you familiar with that journal? A. I'm aware that it exists. Q. Do you review that journal on a regular basis as a part of your clinical and research activities?	5 6 7 8 9 10 11 12 13 14 15 16 17 18	discusses the suitability of substituting cornstarch materials for talc due to perceived issues with talc. Q. Is this an article that you had cited previously, either in your references or your list of literature? A. I did not cite it in my report. I don't know I don't recall if it's in the literature list or not. (Carson Deposition Exhibit 8 marked.) BY MR. ZELLERS: Q. Why did you decide to bring that with you here today?
6 7 8 9 10 11 12 13 14 15 16 17 18	Cancer. The lead author is Mohamed Taher. Q. The Taher paper we have marked as Exhibit 7; is that right? A. Yes. Q. This is something that you were provided by plaintiffs' counsel; is that right? A. Yes. Q. Exhibit 6, Reproductive Sciences, are you familiar with that journal? A. I'm aware that it exists. Q. Do you review that journal on a regular basis as a part of your clinical and research activities? A. No, I don't.	5 6 7 8 9 10 11 12 13 14 15 16 17 18	discusses the suitability of substituting cornstarch materials for talc due to perceived issues with talc. Q. Is this an article that you had cited previously, either in your references or your list of literature? A. I did not cite it in my report. I don't know I don't recall if it's in the literature list or not. (Carson Deposition Exhibit 8 marked.) BY MR. ZELLERS: Q. Why did you decide to bring that with you here today? A. It is in the literature list.
6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	Cancer. The lead author is Mohamed Taher. Q. The Taher paper we have marked as Exhibit 7; is that right? A. Yes. Q. This is something that you were provided by plaintiffs' counsel; is that right? A. Yes. Q. Exhibit 6, Reproductive Sciences, are you familiar with that journal? A. I'm aware that it exists. Q. Do you review that journal on a regular basis as a part of your clinical and research activities? A. No, I don't. Q. Is Reproductive Sciences a	5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	discusses the suitability of substituting cornstarch materials for talc due to perceived issues with talc. Q. Is this an article that you had cited previously, either in your references or your list of literature? A. I did not cite it in my report. I don't know I don't recall if it's in the literature list or not. (Carson Deposition Exhibit 8 marked.) BY MR. ZELLERS: Q. Why did you decide to bring that with you here today? A. It is in the literature list. I ran across it last night, and
6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Cancer. The lead author is Mohamed Taher. Q. The Taher paper we have marked as Exhibit 7; is that right? A. Yes. Q. This is something that you were provided by plaintiffs' counsel; is that right? A. Yes. Q. Exhibit 6, Reproductive Sciences, are you familiar with that journal? A. I'm aware that it exists. Q. Do you review that journal on a regular basis as a part of your clinical and research activities? A. No, I don't. Q. Is Reproductive Sciences a peer-reviewed journal?	5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	discusses the suitability of substituting cornstarch materials for talc due to perceived issues with talc. Q. Is this an article that you had cited previously, either in your references or your list of literature? A. I did not cite it in my report. I don't know I don't recall if it's in the literature list or not. (Carson Deposition Exhibit 8 marked.) BY MR. ZELLERS: Q. Why did you decide to bring that with you here today? A. It is in the literature list. I ran across it last night, and I thought I might need to refer to it during
6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Cancer. The lead author is Mohamed Taher. Q. The Taher paper we have marked as Exhibit 7; is that right? A. Yes. Q. This is something that you were provided by plaintiffs' counsel; is that right? A. Yes. Q. Exhibit 6, Reproductive Sciences, are you familiar with that journal? A. I'm aware that it exists. Q. Do you review that journal on a regular basis as a part of your clinical and research activities? A. No, I don't. Q. Is Reproductive Sciences a peer-reviewed journal? A. I believe it is.	5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	discusses the suitability of substituting cornstarch materials for talc due to perceived issues with talc. Q. Is this an article that you had cited previously, either in your references or your list of literature? A. I did not cite it in my report. I don't know I don't recall if it's in the literature list or not. (Carson Deposition Exhibit 8 marked.) BY MR. ZELLERS: Q. Why did you decide to bring that with you here today? A. It is in the literature list. I ran across it last night, and I thought I might need to refer to it during the deposition.

8 (Pages 26 to 29)

	Page 30		Page 32
1	binder of materials?	1	talcum powder and ovarian cancer, is
2	A. I have here a copy of the	2	something that you undertook when you were
3	recent Canadian position on the safety of	3	retained by plaintiffs' counsel and asked to
4	talcum powder and its relationship to ovarian	4	address the question they gave to you?
5	cancer.	5	A. Yes, it is.
6	Q. When did you review that	6	Q. We will mark the article by
7	document?	7	Blount as Exhibit 11.
8	A. A couple weeks ago, I think.	8	(Carson Deposition Exhibit 11
9	Q. Is that a document that you	9	marked.)
10	were provided by plaintiffs' counsel?	10	BY MR. ZELLERS:
11	A. It was.	11	Q. And you have one more; is that
12	Q. Can I see the document, please?	12	right?
13	We'll mark the draft screening assessment	13	A. Yes, one more, which is this
14	from Health Canada dated December 18th of	14	is an article from the American Journal of
15	2018 as Exhibit 9.	15	Obstetrics and Gynecology from 1974 titled
16	(Carson Deposition Exhibit 9	16	The Ovarian Mesothelioma. It's authored by
17	marked.)	17	Parmley and Woodruff.
18	BY MR. ZELLERS:	18	Q. We'll mark that as Exhibit 12.
19	Q. Any other documents?	19	(Carson Deposition Exhibit 12
20	A. I have a copy of the letter	20	marked.)
21	from the FDA from April 1st, 2014 responding	21	BY MR. ZELLERS:
22	to positions petitions for labeling.	22	
23	Q. This is a letter that has a	23	
23 24		24	that was cited previously by you in either your references or your literature list?
24	stamp on it on the first page, April 1st,	24	your references or your merature list?
	Page 31		Page 33
1	2014, from or strike that to	1	A. Yes.
2	Dr. Epstein from the FDA; is that right?	2	Q. For what strike that.
3	A. Yes.	3	Is this a document that you
4	Q. Let's mark that as Exhibit 10.	4	chose to bring today or were you provided it
5	(Carson Deposition Exhibit 10	5	by plaintiffs' counsel?
6	marked.)	6	A. This is another one I ran
7	BY MR. ZELLERS:	7	across last night and decided to bring along
8	Q. What else?	8	to the depo.
9	A. I have an article authored by	9	Q. Same questions with respect to
10	A.M. Blount which is titled Amphibole Content	10	the Blount article, Exhibit 11: Is this an
11	of Cosmetic and Pharmaceutical Talcs that was	11	article you cite in your references or
12	published in Environmental Health	12	literature?
13	Perspectives in 1991.	13	A. In the literature, yes.
	Q. Is that a journal that you	14	Q. For what purpose have you
14		l	
14 15	review on a regular basis as part of either	15	brought this with you today?
		15 16	A. I thought I might want to refer
15	review on a regular basis as part of either	1	
15 16	review on a regular basis as part of either your clinical practice or your research activities?	16	A. I thought I might want to refer
15 16 17	review on a regular basis as part of either your clinical practice or your research activities?	16 17	A. I thought I might want to refer to it in response to questions here.
15 16 17 18 19	review on a regular basis as part of either your clinical practice or your research activities? A. That one I do look at pretty much.	16 17 18	A. I thought I might want to refer to it in response to questions here. Q. Exhibit 10, the letter from the FDA to Dr. Epstein, April of 2014, for what
15 16 17 18 19 20	review on a regular basis as part of either your clinical practice or your research activities? A. That one I do look at pretty much. Q. Is this an article you were	16 17 18 19	A. I thought I might want to refer to it in response to questions here. Q. Exhibit 10, the letter from the FDA to Dr. Epstein, April of 2014, for what purpose have you brought that here with you
15 16 17 18 19 20 21	review on a regular basis as part of either your clinical practice or your research activities? A. That one I do look at pretty much. Q. Is this an article you were aware of back in 1991?	16 17 18 19 20	A. I thought I might want to refer to it in response to questions here. Q. Exhibit 10, the letter from the FDA to Dr. Epstein, April of 2014, for what purpose have you brought that here with you today?
15 16 17 18 19 20	review on a regular basis as part of either your clinical practice or your research activities? A. That one I do look at pretty much. Q. Is this an article you were	16 17 18 19 20 21	A. I thought I might want to refer to it in response to questions here. Q. Exhibit 10, the letter from the FDA to Dr. Epstein, April of 2014, for what purpose have you brought that here with you today?

9 (Pages 30 to 33)

	Daga 24		Page 20
_	Page 34		Page 36
1	brought here with you today are documents	1	wouldn't be able to tell you for sure. I'm
2	that you wanted to have available to try to	2	sure I ran across these in my own literature
3	respond to the questions that I may ask you?	3	search.
4	A. Yes.	4	Q. Deposition Exhibit 13, we will
5	Q. These documents you all	5	mark the thumb drive that plaintiffs' counsel
6	believe strike that.	6	has brought here today.
7	The documents that you've	7	(Carson Deposition Exhibit 13
8	identified and you've brought with you	8	marked.)
9	have brought with you today, you believe	9	BY MR. ZELLERS:
10	those are supportive of the opinions that you	10	Q. Do you, Dr. Carson, have an
11	are rendering in this matter; is that right?	11	understanding of what's on the thumb drive
12	A. Yes.	12	we've marked as Exhibit 13?
13	Q. The documents on your	13	A. My understanding is this is
14	literature list, what we have marked as	14	copies of the documents on the literature
15	Exhibit 4, are those documents that were	15	list.
16	provided to you by plaintiffs' counsel?	16	Q. When were you first retained by
17	A. Some were.	17	anyone regarding the talc/ovarian cancer
18	Q. The documents on this list that	18	litigation?
19	were not provided by plaintiffs' counsel, did	19	A. In October of 2018.
20	you find those through a literature search?	20	Q. Who contacted you?
21	A. Yes.	21	A. I was contacted by an attorney
22	Q. Are you able to distinguish for	22	named Russ Abney.
23	us which documents on your literature list,	23	Q. Who is Mr. Abney, if you know?
24	Exhibit 4, came from plaintiffs' counsel and	24	A. Mr. Abney is a lawyer who used
	Page 35		Page 37
1	which items on the literature list you came	1	to work in the Houston area and with whom I
2	up with?	2	had some dealings years ago; and since that
3	A. To some extent.	3	time he has become involved in this talc
4	Q. So if we went through item by	4	litigation in some way, was aware of me as a
5	item, you believe you could distinguish	5	potential expert witness, and contacted me
6	between what was provided to you by	6	regarding my interest and availability.
7	plaintiffs and what you found on your own?	7	Q. What matters have you worked on
8	A. For some, but not all of them.	8	with Mr. Abney in the past?
9	Q. Have you reviewed all of the	9	A. I think it would have been back
10	materials that are listed on your literature	10	in the 1990s, and I frankly don't recall what
11	list?	11	cases we worked on, but there were one or
12	A. I have reviewed all of them,	12	maybe two cases.
13	yes.	13	Q. When in October of 2018 were
14	Q. Have you reviewed all of the	14	you contacted by Mr. Abney?
15	materials that are on your reference list?	15	MS. O'DELL: Object to the
16	A. Yes.	16	form.
17	Q. The materials on your reference	17	A. I believe it was either the
18	list, is it the same that some were provided	18	14th or 15th of October.
19	to you by plaintiffs' counsel and some you	19	BY MR. ZELLERS:
20	found on your own?	20	Q. How do you remember with that
21	A. I think there may be one or two	21	precision?
22	references that I didn't have before I saw	22	A. I have an e-mail that relates
23	them in the share file that may have been	23	to a phone call which was our initial
24	provided by plaintiffs' counsel, but I	24	contact.

10 (Pages 34 to 37)

	Page 38		Page 40
1	Q. Mr. Abney at some point asked	1	doing a review? What does that mean?
2	you to address the question that you told us	2	A. Well, I felt that I was hired
3	before: Does the habitual use of talcum	3	as a witness at that point and that's when I
4	powder cause ovarian cancer?	4	would begin my billable hours on this case.
5	Is that right?	5	Q. When was that? Sometime in
6	MS. O'DELL: Object to the	6	later October of late October of 2018?
7	form.	7	A. It was within a few days after
8	A. Well, he talked to me generally	8	our first meeting, still in October.
9	about the case that was proceeding, and I	9	Q. What did you do to answer the
10	discussed with him what my understanding of	10	question? What was your methodology?
11	those things was and what the kind of	11	A. Well, initially I decided to do
12	opinions I would be able to render would be.	12	a general literature search on the question
13	And he suggested that he set up a meeting	13	to see what research had been performed, what
14	between me and members of plaintiffs'	14	reports had been written, what the quality of
15	counsel.	15	that research was.
16	BY MR. ZELLERS:	16	
17	Q. When Mr. Abney called you	17	A. Immediately. I was curious.
18	middle of October of 2018, talcum powder and	18	I began to assemble the
19	any relationship or association that it may	19	available literature and review it on a
20	have to ovarian cancer had not been a focus	20	piecemeal basis through the subsequent time
21	of your research or study; is that right?	21	period; the next couple of weeks I reviewed a
22	A. That's right.	22	lot of it.
23	Q. It had not been a part of your	23	Q. What did you search for when
24	clinical practice, right?	24	you did this general literature search?
24		24	
24	clinical practice, right? Page 39		you did this general literature search? Page 41
	clinical practice, right? Page 39 A. That's correct.		you did this general literature search? Page 41 A. I searched under various search
1	clinical practice, right? Page 39 A. That's correct. Q. When did you meet with the		you did this general literature search? Page 41 A. I searched under various search terms, including "talc," including "ovarian
1 2 3	clinical practice, right? Page 39 A. That's correct. Q. When did you meet with the larger group of plaintiffs' counsel?		you did this general literature search? Page 41 A. I searched under various search terms, including "talc," including "ovarian cancer," the relationship between the two.
1 2 3 4	A. That's correct. Q. When did you meet with the larger group of plaintiffs' counsel? A. I believe we had a telephone		you did this general literature search? Page 41 A. I searched under various search terms, including "talc," including "ovarian cancer," the relationship between the two. As I became more familiar with the
1 2 3 4 5	A. That's correct. Q. When did you meet with the larger group of plaintiffs' counsel? A. I believe we had a telephone meeting on the 16th of October. I'm not		you did this general literature search? Page 41 A. I searched under various search terms, including "talc," including "ovarian cancer," the relationship between the two. As I became more familiar with the literature, I expanded that search into other
1 2 3 4 5	A. That's correct. Q. When did you meet with the larger group of plaintiffs' counsel? A. I believe we had a telephone meeting on the 16th of October. I'm not sure. I have to		you did this general literature search? Page 41 A. I searched under various search terms, including "talc," including "ovarian cancer," the relationship between the two. As I became more familiar with the literature, I expanded that search into other topics.
1 2 3 4 5 6	A. That's correct. Q. When did you meet with the larger group of plaintiffs' counsel? A. I believe we had a telephone meeting on the 16th of October. I'm not sure. I have to Q. That's right now I just want		you did this general literature search? Page 41 A. I searched under various search terms, including "talc," including "ovarian cancer," the relationship between the two. As I became more familiar with the literature, I expanded that search into other topics. As I became I was already
1 2 3 4 5 6 7 8	A. That's correct. Q. When did you meet with the larger group of plaintiffs' counsel? A. I believe we had a telephone meeting on the 16th of October. I'm not sure. I have to Q. That's right now I just want estimates.	1 2 3 4 5 6 7	you did this general literature search? Page 41 A. I searched under various search terms, including "talc," including "ovarian cancer," the relationship between the two. As I became more familiar with the literature, I expanded that search into other topics. As I became I was already aware of issues related to the inclusion of
1 2 3 4 5 6 7 8	A. That's correct. Q. When did you meet with the larger group of plaintiffs' counsel? A. I believe we had a telephone meeting on the 16th of October. I'm not sure. I have to Q. That's right now I just want estimates. A. Okay.	1 2 3 4 5 6 7 8	you did this general literature search? Page 41 A. I searched under various search terms, including "talc," including "ovarian cancer," the relationship between the two. As I became more familiar with the literature, I expanded that search into other topics. As I became I was already aware of issues related to the inclusion of asbestos in talc deposits, and so I expanded
1 2 3 4 5 6 7 8 9	A. That's correct. Q. When did you meet with the larger group of plaintiffs' counsel? A. I believe we had a telephone meeting on the 16th of October. I'm not sure. I have to Q. That's right now I just want estimates. A. Okay. Q. And so I don't as long as	1 2 3 4 5 6 7 8 9	you did this general literature search? Page 41 A. I searched under various search terms, including "talc," including "ovarian cancer," the relationship between the two. As I became more familiar with the literature, I expanded that search into other topics. As I became I was already aware of issues related to the inclusion of asbestos in talc deposits, and so I expanded my search into that part of the literature
1 2 3 4 5 6 7 8 9 10 11	A. That's correct. Q. When did you meet with the larger group of plaintiffs' counsel? A. I believe we had a telephone meeting on the 16th of October. I'm not sure. I have to Q. That's right now I just want estimates. A. Okay. Q. And so I don't as long as you're reasonably comfortable that it was in	1 2 3 4 5 6 7 8 9	you did this general literature search? Page 41 A. I searched under various search terms, including "tale," including "ovarian cancer," the relationship between the two. As I became more familiar with the literature, I expanded that search into other topics. As I became I was already aware of issues related to the inclusion of asbestos in talc deposits, and so I expanded my search into that part of the literature that relates to asbestos in talc or asbestos
1 2 3 4 5 6 7 8 9 10 11 12	A. That's correct. Q. When did you meet with the larger group of plaintiffs' counsel? A. I believe we had a telephone meeting on the 16th of October. I'm not sure. I have to Q. That's right now I just want estimates. A. Okay. Q. And so I don't as long as you're reasonably comfortable that it was in that time frame.	1 2 3 4 5 6 7 8 9 10 11 12	you did this general literature search? Page 41 A. I searched under various search terms, including "tale," including "ovarian cancer," the relationship between the two. As I became more familiar with the literature, I expanded that search into other topics. As I became I was already aware of issues related to the inclusion of asbestos in talc deposits, and so I expanded my search into that part of the literature that relates to asbestos in talc or asbestos in ovarian cancer.
1 2 3 4 5 6 7 8 9 10 11 12 13	A. That's correct. Q. When did you meet with the larger group of plaintiffs' counsel? A. I believe we had a telephone meeting on the 16th of October. I'm not sure. I have to Q. That's right now I just want estimates. A. Okay. Q. And so I don't as long as you're reasonably comfortable that it was in that time frame. A. It was mid October.	1 2 3 4 5 6 7 8 9 10 11 12 13	you did this general literature search? Page 41 A. I searched under various search terms, including "talc," including "ovarian cancer," the relationship between the two. As I became more familiar with the literature, I expanded that search into other topics. As I became I was already aware of issues related to the inclusion of asbestos in talc deposits, and so I expanded my search into that part of the literature that relates to asbestos in talc or asbestos in ovarian cancer. As I felt my opinions would
1 2 3 4 5 6 7 8 9 10 11 12 13 14	A. That's correct. Q. When did you meet with the larger group of plaintiffs' counsel? A. I believe we had a telephone meeting on the 16th of October. I'm not sure. I have to Q. That's right now I just want estimates. A. Okay. Q. And so I don't as long as you're reasonably comfortable that it was in that time frame. A. It was mid October. Q. That's fine.	1 2 3 4 5 6 7 8 9 10 11 12 13 14	you did this general literature search? Page 41 A. I searched under various search terms, including "talc," including "ovarian cancer," the relationship between the two. As I became more familiar with the literature, I expanded that search into other topics. As I became I was already aware of issues related to the inclusion of asbestos in talc deposits, and so I expanded my search into that part of the literature that relates to asbestos in talc or asbestos in ovarian cancer. As I felt my opinions would need to extend into cancer and carcinogenesis
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15	A. That's correct. Q. When did you meet with the larger group of plaintiffs' counsel? A. I believe we had a telephone meeting on the 16th of October. I'm not sure. I have to Q. That's right now I just want estimates. A. Okay. Q. And so I don't as long as you're reasonably comfortable that it was in that time frame. A. It was mid October. Q. That's fine. When were you asked the	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15	you did this general literature search? Page 41 A. I searched under various search terms, including "talc," including "ovarian cancer," the relationship between the two. As I became more familiar with the literature, I expanded that search into other topics. As I became I was already aware of issues related to the inclusion of asbestos in talc deposits, and so I expanded my search into that part of the literature that relates to asbestos in talc or asbestos in ovarian cancer. As I felt my opinions would need to extend into cancer and carcinogenesis in general, I did some search into ovarian
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	A. That's correct. Q. When did you meet with the larger group of plaintiffs' counsel? A. I believe we had a telephone meeting on the 16th of October. I'm not sure. I have to Q. That's right now I just want estimates. A. Okay. Q. And so I don't as long as you're reasonably comfortable that it was in that time frame. A. It was mid October. Q. That's fine. When were you asked the question that the plaintiffs' lawyers wanted	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	you did this general literature search? Page 41 A. I searched under various search terms, including "talc," including "ovarian cancer," the relationship between the two. As I became more familiar with the literature, I expanded that search into other topics. As I became I was already aware of issues related to the inclusion of asbestos in talc deposits, and so I expanded my search into that part of the literature that relates to asbestos in talc or asbestos in ovarian cancer. As I felt my opinions would need to extend into cancer and carcinogenesis in general, I did some search into ovarian cancer specifically and general
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	A. That's correct. Q. When did you meet with the larger group of plaintiffs' counsel? A. I believe we had a telephone meeting on the 16th of October. I'm not sure. I have to Q. That's right now I just want estimates. A. Okay. Q. And so I don't as long as you're reasonably comfortable that it was in that time frame. A. It was mid October. Q. That's fine. When were you asked the question that the plaintiffs' lawyers wanted you to try to answer in this litigation?	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	Page 41 A. I searched under various search terms, including "talc," including "ovarian cancer," the relationship between the two. As I became more familiar with the literature, I expanded that search into other topics. As I became I was already aware of issues related to the inclusion of asbestos in talc deposits, and so I expanded my search into that part of the literature that relates to asbestos in talc or asbestos in ovarian cancer. As I felt my opinions would need to extend into cancer and carcinogenesis in general, I did some search into ovarian cancer specifically and general carcinogenesis to see what the current state
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	A. That's correct. Q. When did you meet with the larger group of plaintiffs' counsel? A. I believe we had a telephone meeting on the 16th of October. I'm not sure. I have to Q. That's right now I just want estimates. A. Okay. Q. And so I don't as long as you're reasonably comfortable that it was in that time frame. A. It was mid October. Q. That's fine. When were you asked the question that the plaintiffs' lawyers wanted you to try to answer in this litigation? A. Well, after the meeting we	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	you did this general literature search? Page 41 A. I searched under various search terms, including "talc," including "ovarian cancer," the relationship between the two. As I became more familiar with the literature, I expanded that search into other topics. As I became I was already aware of issues related to the inclusion of asbestos in talc deposits, and so I expanded my search into that part of the literature that relates to asbestos in talc or asbestos in ovarian cancer. As I felt my opinions would need to extend into cancer and carcinogenesis in general, I did some search into ovarian cancer specifically and general carcinogenesis to see what the current state of the art was regarding that in the
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	A. That's correct. Q. When did you meet with the larger group of plaintiffs' counsel? A. I believe we had a telephone meeting on the 16th of October. I'm not sure. I have to Q. That's right now I just want estimates. A. Okay. Q. And so I don't as long as you're reasonably comfortable that it was in that time frame. A. It was mid October. Q. That's fine. When were you asked the question that the plaintiffs' lawyers wanted you to try to answer in this litigation? A. Well, after the meeting we parted ways and then made contact again a few	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	you did this general literature search? Page 41 A. I searched under various search terms, including "talc," including "ovarian cancer," the relationship between the two. As I became more familiar with the literature, I expanded that search into other topics. As I became I was already aware of issues related to the inclusion of asbestos in talc deposits, and so I expanded my search into that part of the literature that relates to asbestos in talc or asbestos in ovarian cancer. As I felt my opinions would need to extend into cancer and carcinogenesis in general, I did some search into ovarian cancer specifically and general carcinogenesis to see what the current state of the art was regarding that in the literature.
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	A. That's correct. Q. When did you meet with the larger group of plaintiffs' counsel? A. I believe we had a telephone meeting on the 16th of October. I'm not sure. I have to Q. That's right now I just want estimates. A. Okay. Q. And so I don't as long as you're reasonably comfortable that it was in that time frame. A. It was mid October. Q. That's fine. When were you asked the question that the plaintiffs' lawyers wanted you to try to answer in this litigation? A. Well, after the meeting we parted ways and then made contact again a few days later, and I was told that they were	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	Page 41 A. I searched under various search terms, including "talc," including "ovarian cancer," the relationship between the two. As I became more familiar with the literature, I expanded that search into other topics. As I became I was already aware of issues related to the inclusion of asbestos in talc deposits, and so I expanded my search into that part of the literature that relates to asbestos in talc or asbestos in ovarian cancer. As I felt my opinions would need to extend into cancer and carcinogenesis in general, I did some search into ovarian cancer specifically and general carcinogenesis to see what the current state of the art was regarding that in the literature. I looked at some issues of
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	A. That's correct. Q. When did you meet with the larger group of plaintiffs' counsel? A. I believe we had a telephone meeting on the 16th of October. I'm not sure. I have to Q. That's right now I just want estimates. A. Okay. Q. And so I don't as long as you're reasonably comfortable that it was in that time frame. A. It was mid October. Q. That's fine. When were you asked the question that the plaintiffs' lawyers wanted you to try to answer in this litigation? A. Well, after the meeting we parted ways and then made contact again a few days later, and I was told that they were interested in me going ahead and doing a	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	you did this general literature search? A. I searched under various search terms, including "talc," including "ovarian cancer," the relationship between the two. As I became more familiar with the literature, I expanded that search into other topics. As I became I was already aware of issues related to the inclusion of asbestos in talc deposits, and so I expanded my search into that part of the literature that relates to asbestos in talc or asbestos in ovarian cancer. As I felt my opinions would need to extend into cancer and carcinogenesis in general, I did some search into ovarian cancer specifically and general carcinogenesis to see what the current state of the art was regarding that in the literature. I looked at some issues of mining practices.
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. That's correct. Q. When did you meet with the larger group of plaintiffs' counsel? A. I believe we had a telephone meeting on the 16th of October. I'm not sure. I have to Q. That's right now I just want estimates. A. Okay. Q. And so I don't as long as you're reasonably comfortable that it was in that time frame. A. It was mid October. Q. That's fine. When were you asked the question that the plaintiffs' lawyers wanted you to try to answer in this litigation? A. Well, after the meeting we parted ways and then made contact again a few days later, and I was told that they were interested in me going ahead and doing a review and starting to establish opinions.	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Page 41 A. I searched under various search terms, including "talc," including "ovarian cancer," the relationship between the two. As I became more familiar with the literature, I expanded that search into other topics. As I became I was already aware of issues related to the inclusion of asbestos in talc deposits, and so I expanded my search into that part of the literature that relates to asbestos in talc or asbestos in ovarian cancer. As I felt my opinions would need to extend into cancer and carcinogenesis in general, I did some search into ovarian cancer specifically and general carcinogenesis to see what the current state of the art was regarding that in the literature. I looked at some issues of mining practices. I looked at the Johnson &
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	A. That's correct. Q. When did you meet with the larger group of plaintiffs' counsel? A. I believe we had a telephone meeting on the 16th of October. I'm not sure. I have to Q. That's right now I just want estimates. A. Okay. Q. And so I don't as long as you're reasonably comfortable that it was in that time frame. A. It was mid October. Q. That's fine. When were you asked the question that the plaintiffs' lawyers wanted you to try to answer in this litigation? A. Well, after the meeting we parted ways and then made contact again a few days later, and I was told that they were interested in me going ahead and doing a	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Page 41 A. I searched under various search terms, including "talc," including "ovarian cancer," the relationship between the two. As I became more familiar with the literature, I expanded that search into other topics. As I became I was already aware of issues related to the inclusion of asbestos in talc deposits, and so I expanded my search into that part of the literature that relates to asbestos in talc or asbestos in ovarian cancer. As I felt my opinions would need to extend into cancer and carcinogenesis in general, I did some search into ovarian cancer specifically and general carcinogenesis to see what the current state of the art was regarding that in the literature. [I looked at some issues of mining practices.]

11 (Pages 38 to 41)

Page 42		Page 44
I looked through old notes and	1	review of draft versions of my report and
lecture files that I had for information that	2	comments, in particular
I've used or accessed previously in my	3	Q. Don't tell me about the
	4	comments.
	5	A. Okay.
	6	Q. I don't want to know what the
extensive search.	7	lawyers may have told you.
Q. You reviewed these materials	8	Did the comments come from the
	9	lawyers for plaintiffs or did they come from
	10	other people?
		A. They came from the lawyers.
		They also came from a few of my colleagues
		Q. Did you share your report with
		some of your colleagues?
		A. I let a few people read it and
		I talked to them about it.
		Q. Are the opinions your opinions?
		A. Yes, they are.
		Q. Have you told me, you know,
		generally what you have done to formulate
		your opinions in this matter?
		A. Yes, I think so.
		Q. You did all of this over a
		30-day period; is that right?
of the search materials that are not relevant	21	50-day period, is that right:
Page 43		Page 45
or interesting to me and then refine my	1	A. Yes.
		Q. All right. You have no
	3	invoices, correct?
pertinent in my opinion, until I satisfy	4	A. That's correct.
myself that I have pretty much covered the	5	Q. Is it typical that you'll work
waterfront so to speak in terms of a	6	on a matter for some number of months and no
literature review.	7	generate any invoices?
Q. You did your literature review.	8	A. Yes.
You reviewed the Johnson & Johnson website	9	Q. You are billing your time at
and the other materials that you have told us	10	what rate?
about.	11	A. \$450 per hour.
Did you then formulate your	12	Q. Can you estimate for us the
opinions and set them down in your report	13	number of hours that you have spent doing
which we marked as Exhibit 2?	14	your literature review, formulating your
A. I did. I began writing as I	15	opinions, and writing your report?
reviewed the literature and continued to take	16	A. There's still some tallying I
notes which, through a continuous editing	17	need to do from my calendar, but it's between
process, eventually became my report.	18	150 and 180 hours.
	19	Q. Does that include your meetings
O. Did you prepare your report?		Z. Dood and morade Jour mounings
Q. Did you prepare your report? A. I did.	2.0	and communications with plaintiffs' counsel?
A. I did.	20 21	and communications with plaintiffs' counsel? A Yes, that's up until today.
A. I did.Q. Did anyone assist you in the	21	A. Yes, that's up until today.
A. I did.		
_	I looked through old notes and lecture files that I had for information that I've used or accessed previously in my professional capacity for information that was pertinent. Just a very dendritic kind of extensive search. Q. You reviewed these materials that you have told us about and then did you prepare your report? A. At that point I well, the literature review took several stages. Typically when you perform a review like this, you end up with a I do a very general sort of approach to a review, so I get much more than will be pertinent to my review eventually. I find that a valuable approach because it allows me to find things I wouldn't otherwise find or look for or know to look for. And then I'm able to cull through that information and discard pieces of the search materials that are not relevant Page 43 or interesting to me and then refine my search and redo it, extending it into different areas that have now become pertinent in my opinion, until I satisfy myself that I have pretty much covered the waterfront so to speak in terms of a literature review. Q. You did your literature review. You reviewed the Johnson & Johnson website and the other materials that you have told us about. Did you then formulate your opinions and set them down in your report which we marked as Exhibit 2? A. I did. I began writing as I reviewed the literature and continued to take	I looked through old notes and lecture files that I had for information that I've used or accessed previously in my professional capacity for information that was pertinent. Just a very dendritic kind of extensive search. Q. You reviewed these materials that you have told us about and then did you prepare your report? A. At that point I well, the literature review took several stages. Typically when you perform a review like this, you end up with a I do a very general sort of approach to a review, so I get much more than will be pertinent to my review eventually. I find that a valuable approach because it allows me to find things I wouldn't otherwise find or look for or know to look for. And then I'm able to cull through that information and discard pieces of the search materials that are not relevant Page 43 or interesting to me and then refine my search and redo it, extending it into different areas that have now become pertinent in my opinion, until I satisfy myself that I have pretty much covered the waterfront so to speak in terms of a literature review. Q. You did your literature review. You reviewed the Johnson & Johnson website and the other materials that you have told us about. Did you then formulate your opinions and set them down in your report which we marked as Exhibit 2? A. I did. I began writing as I reviewed the literature and continued to take

	Page 46		Page 48
1	A. No.	1	A. I have not had any discussions
2	Q. What other plaintiff lawyers	2	with Dr. Dydek. We may have met previously,
3	have you met with or talked with as part of	3	but I don't recall.
4	your formulating your opinions and doing your	4	Q. Any previous meeting with
5	literature review?	5	Dr. Dydek, did it relate to this litigation?
6	A. We've had a number of	6	A. No.
7	conference calls where there were several of	7	Q. Did it relate to expert witness
8	these attorneys' colleagues on the line, but	8	work that you were doing?
9	in terms of in-person meetings, those have	9	A. No.
10	been with Ms. O'Dell and Ms. Thompson,	10	Q. Do you know what the
11	Dr. Thompson.	11	relationship is, if any, between Dr. Thompson
12	Q. How many meetings have you had	12	and Dr. Dydek?
13	with Ms. O'Dell?	13	A. I don't know of any
14	A. Three.	14	relationship outside of his work as an expert
15	Q. How many meetings have you had	15	witness in related litigation.
16	with Dr. Thompson?	16	Q. Dr. Crowley, do you know
17	A. Three.	17	Michael Crowley?
18	Q. Did you know Dr. Thompson	18	A. I know of Dr. Crowley.
19	before you were retained in this matter?	19	Q. Did you know of Dr. Crowley
20	A. I did not.	20	before you were retained in the talcum powder
21		21	
22		22	litigation? A. No.
23	this litigation that you are aware of	23	
23 24	strike that.	24	Q. Have you ever met with
24	Any other plaintiff lawyers in	24	Dr. Crowley?
	Page 47		Page 49
1	this matter that you've had communications	1	A. I have not.
2	with other than what you have told us?	2	Q. Ever talked with Dr. Crowley?
3	A. No.	3	A. I have not.
4	Q. Do you have any social	4	Q. You reviewed his report as part
5	relationship with any of the plaintiffs'	5	of your review in this matter; is that right?
6	counsel?	6	A. That's correct.
7	A. No.	7	Q. Do you know who any of the
8	Q. Your relationship with	8	other experts are in this litigation for
9	Dr. Thompson is just the three meetings that	9	plaintiffs?
10	you have been involved in with her?	10	A. Well, I know there are a number
11	A. Well, we've exchanged e-mail	11	of people who have generated reports that I
10	communications, but other than that, no.	12	have also reviewed.
12			
		13	
13	Q. Have you met with or talked	13 14	Q. What reports have you reviewed
13 14	Q. Have you met with or talked with any other expert witness for plaintiffs?	14	Q. What reports have you reviewed from plaintiffs' other experts?
13 14 15	Q. Have you met with or talkedwith any other expert witness for plaintiffs?A. No, I have not.	14 15	Q. What reports have you reviewed from plaintiffs' other experts? A. Well, I've reviewed several
13 14 15 16	Q. Have you met with or talked with any other expert witness for plaintiffs?A. No, I have not.Q. Do you know who Thomas Dydek	14 15 16	Q. What reports have you reviewed from plaintiffs' other experts? A. Well, I've reviewed several reports from Dr. Longo, who's done work on
13 14 15 16 17	Q. Have you met with or talked with any other expert witness for plaintiffs?A. No, I have not.Q. Do you know who Thomas Dydek is?	14 15 16 17	Q. What reports have you reviewed from plaintiffs' other experts? A. Well, I've reviewed several reports from Dr. Longo, who's done work on the presence of asbestos in talc products and
13 14 15 16 17 18	 Q. Have you met with or talked with any other expert witness for plaintiffs? A. No, I have not. Q. Do you know who Thomas Dydek is? A. Yes. 	14 15 16 17 18	Q. What reports have you reviewed from plaintiffs' other experts? A. Well, I've reviewed several reports from Dr. Longo, who's done work on the presence of asbestos in tale products and related things. I think he's the only other
13 14 15 16 17 18 19	 Q. Have you met with or talked with any other expert witness for plaintiffs? A. No, I have not. Q. Do you know who Thomas Dydek is? A. Yes. Q. Who is Thomas Dydek? 	14 15 16 17 18 19	Q. What reports have you reviewed from plaintiffs' other experts? A. Well, I've reviewed several reports from Dr. Longo, who's done work on the presence of asbestos in talc products and related things. I think he's the only other expert that I'm aware of at this point.
13 14 15 16 17 18 19 20	 Q. Have you met with or talked with any other expert witness for plaintiffs? A. No, I have not. Q. Do you know who Thomas Dydek is? A. Yes. Q. Who is Thomas Dydek? A. He is a toxicologist. 	14 15 16 17 18 19 20	Q. What reports have you reviewed from plaintiffs' other experts? A. Well, I've reviewed several reports from Dr. Longo, who's done work on the presence of asbestos in talc products and related things. I think he's the only other expert that I'm aware of at this point. Q. Well, you're aware of
13 14 15 16 17 18 19 20 21	 Q. Have you met with or talked with any other expert witness for plaintiffs? A. No, I have not. Q. Do you know who Thomas Dydek is? A. Yes. Q. Who is Thomas Dydek? A. He is a toxicologist. Q. Where does he practice? 	14 15 16 17 18 19 20 21	Q. What reports have you reviewed from plaintiffs' other experts? A. Well, I've reviewed several reports from Dr. Longo, who's done work on the presence of asbestos in talc products and related things. I think he's the only other expert that I'm aware of at this point. Q. Well, you're aware of Dr. Crowley?
13 14 15 16 17 18 19 20	 Q. Have you met with or talked with any other expert witness for plaintiffs? A. No, I have not. Q. Do you know who Thomas Dydek is? A. Yes. Q. Who is Thomas Dydek? A. He is a toxicologist. 	14 15 16 17 18 19 20	Q. What reports have you reviewed from plaintiffs' other experts? A. Well, I've reviewed several reports from Dr. Longo, who's done work on the presence of asbestos in talc products and related things. I think he's the only other expert that I'm aware of at this point. Q. Well, you're aware of

13 (Pages 46 to 49)

Page 50	Page
or transcripts from Dr. Dydek?	1 that you're aware of?
or transcripts from Dr. Dydek? A. Yes, I reviewed an expert report that he provided before I got involved in this case. Q. Did you review that report before you prepared your report? A. Yes. Q. Did you review Dr. Crowley's report before you prepared your report?	that you're aware of? A. No. Q. Are you aware of any of the experts for defendants in the talcum powde litigation? A. No. Q. Have you reviewed any reports from any of the experts in the talcum powde litigation? A. I have not.
report that he provided before I got involved	Q. Are you aware of any of the
4 in this case.	experts for defendants in the talcum powder
Q. Did you review that report	5 litigation?
before you prepared your report?	6 A. No.
7 (A.) (Yes.)	Q. Have you reviewed any reports
8 Q. Did you review Dr. Crowley's	from any of the experts in the talcum power
9 report before you prepared your report?	9 litigation?
O A. Yes.	A. I have not.
1 Q. And you reviewed Dr. Longo's	Q. Have you reviewed any of the
report before you prepared your report; is	transcripts of defense experts in the talcum
that right?	powder litigation?
4 A. (I've reviewed one report.)	A. I've reviewed some deposition
There was another one that became available	transcripts of various witnesses.
6 after.	Q. Those witnesses are all listed
7 Q. The second report is what you	in either your references or your literature;
brought here with you today and we marked as	is that right?
Exhibit 5; is that right?	19 A. Yes.
0 (A.) (Yes.)	Q. Did you review the entire
Q. Any other plaintiff experts	transcripts of the witnesses that you've
that you're aware of?	identified?
A. Not that I can think of, no.	A. I think for the most part I
4 Q. Any other reports from	would say yes.
Page 51	Page
	Page O. Did you review the exhibits to
plaintiffs' experts that you have reviewed? A. Well, there's a there is an article that's been submitted for publication which I consider a piece of the scientific literature. You mentioned Dr. Saed earlier, and I know that he has a relationship with	
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14 (Pages 50 to 53)

	Page 54		Page 56
1	MS. O'DELL: Object to the	1	A. Probably 5%.
1 2 3 4 5 6 7 8	form.	2	Q. What percent of your income
3	Excuse me, I'm sorry,	3	comes from the work that you do as a
4	gentlemen. Give me just one second to	4	consultant?
5	object if I need to.	5	A. Of course it varies quite a bit
6	THE WITNESS: Sure.	6	from moment to moment, but it would be less
7	MS. O'DELL: Thank you.	7	than 10%.
8	BY MR. ZELLERS:	8	Q. Have you ever testified at
9	Q. Did you consider the literature	9	trial?
10	and the sources that refuted that association	10	A. Yes.
11	or causal relationship?	11	Q. On how many occasions?
12	A. I tried to consider all the	12	A. Probably ten.
13	available literature.	13	Q. The 30 to 35 depositions that
14	Q. When you wrote your report	14	you've given previously, those have been in
15	setting forth your opinions, did you set	15	the context of you providing litigation
16	forth the sources that refuted the	16	consulting services; is that right?
17	propositions you were making?	17	A. In terms of expert testimony,
18	A. I cited several sources that on	18	yes.
19	the surface might seem to refute my opinions.	19	Q. The trial appearances that
20	Q. And you believe that is	20	you've made, are those also in your capacity
21	contained in your report which we marked as	21	as an expert witness?
22	Exhibit 2; is that right?	22	A. Yes.
23	A. Yes.	23	
24		24	Q. Have you been involved in other litigations?
24	Q. Have you been involved in any	24	nugations:
	Page 55		Page 57
1	other talcum powder litigation other than	1	A. Yes.
2	this talc MDL matter that Mr. Abney talked to	2	Q. What other litigations have you
3	you about?	3	been involved in as an expert?
4	A. No, I haven't.	4	A. Well, I've been asked to
5	Q. In the 30 to 35 occasions that	5	provide opinions and testify in a number of
6	you've testified in the past, have any of	6	cases, most of which involved personal injury
7	those been on issues relating to talcum	7	in the occupational setting or environmental
8	powder and any association between talcum	8	exposures.
9	powder and ovarian cancer?	9	Q. Has the majority of your expert
10	A. No.	10	work in the occupational setting and for
	11. 110.		
11	Q. You are not an expert in	11	environmental exposures been on behalf of
		11 12	environmental exposures been on behalf of plaintiffs?
11	Q. You are not an expert in	1	
11 12	Q. You are not an expert in asbestos, correct?	12	plaintiffs?
11 12 13	Q. You are not an expert in asbestos, correct? MS. O'DELL: Object to the form.	12 13	plaintiffs? A. No, it's been split about 50/50, plaintiff and defense.
11 12 13 14	 Q. You are not an expert in asbestos, correct? MS. O'DELL: Object to the form. A. I'm an occupational medicine 	12 13 14	plaintiffs? A. No, it's been split about 50/50, plaintiff and defense. Q. Have you ever been retained in
11 12 13 14 15	 Q. You are not an expert in asbestos, correct? MS. O'DELL: Object to the form. A. I'm an occupational medicine physician, and I have a significant amount of 	12 13 14 15	plaintiffs? A. No, it's been split about 50/50, plaintiff and defense.
11 12 13 14 15 16	Q. You are not an expert in asbestos, correct? MS. O'DELL: Object to the form. A. I'm an occupational medicine physician, and I have a significant amount of awareness and training regarding asbestos as	12 13 14 15 16	plaintiffs? A. No, it's been split about 50/50, plaintiff and defense. Q. Have you ever been retained in a case involving cosmetic products? A. No.
11 12 13 14 15 16 17	 Q. You are not an expert in asbestos, correct? MS. O'DELL: Object to the form. A. I'm an occupational medicine physician, and I have a significant amount of awareness and training regarding asbestos as it relates to occupational exposures and 	12 13 14 15 16 17 18	plaintiffs? A. No, it's been split about 50/50, plaintiff and defense. Q. Have you ever been retained in a case involving cosmetic products? A. No. Q. Your curriculum vitae that we
11 12 13 14 15 16 17 18 19	 Q. You are not an expert in asbestos, correct? MS. O'DELL: Object to the form. A. I'm an occupational medicine physician, and I have a significant amount of awareness and training regarding asbestos as it relates to occupational exposures and general environmental exposures, but I don't 	12 13 14 15 16 17 18 19	plaintiffs? A. No, it's been split about 50/50, plaintiff and defense. Q. Have you ever been retained in a case involving cosmetic products? A. No. Q. Your curriculum vitae that we marked as Exhibit 3, is it correct and up to
11 12 13 14 15 16 17 18 19 20	Q. You are not an expert in asbestos, correct? MS. O'DELL: Object to the form. A. I'm an occupational medicine physician, and I have a significant amount of awareness and training regarding asbestos as it relates to occupational exposures and general environmental exposures, but I don't consider myself an asbestos expert.	12 13 14 15 16 17 18 19 20	plaintiffs? A. No, it's been split about 50/50, plaintiff and defense. Q. Have you ever been retained in a case involving cosmetic products? A. No. Q. Your curriculum vitae that we marked as Exhibit 3, is it correct and up to date?
11 12 13 14 15 16 17 18 19 20 21	Q. You are not an expert in asbestos, correct? MS. O'DELL: Object to the form. A. I'm an occupational medicine physician, and I have a significant amount of awareness and training regarding asbestos as it relates to occupational exposures and general environmental exposures, but I don't consider myself an asbestos expert. BY MR. ZELLERS:	12 13 14 15 16 17 18 19 20 21	plaintiffs? A. No, it's been split about 50/50, plaintiff and defense. Q. Have you ever been retained in a case involving cosmetic products? A. No. Q. Your curriculum vitae that we marked as Exhibit 3, is it correct and up to date? A. It was up to date at the time
11 12 13 14 15 16 17 18 19 20 21 22	Q. You are not an expert in asbestos, correct? MS. O'DELL: Object to the form. A. I'm an occupational medicine physician, and I have a significant amount of awareness and training regarding asbestos as it relates to occupational exposures and general environmental exposures, but I don't consider myself an asbestos expert. BY MR. ZELLERS: Q. What percentage of your time do	12 13 14 15 16 17 18 19 20 21 22	plaintiffs? A. No, it's been split about 50/50, plaintiff and defense. Q. Have you ever been retained in a case involving cosmetic products? A. No. Q. Your curriculum vitae that we marked as Exhibit 3, is it correct and up to date? A. It was up to date at the time of submission of my report in the end of
11 12 13 14 15 16 17 18 19 20 21	Q. You are not an expert in asbestos, correct? MS. O'DELL: Object to the form. A. I'm an occupational medicine physician, and I have a significant amount of awareness and training regarding asbestos as it relates to occupational exposures and general environmental exposures, but I don't consider myself an asbestos expert. BY MR. ZELLERS:	12 13 14 15 16 17 18 19 20 21	plaintiffs? A. No, it's been split about 50/50, plaintiff and defense. Q. Have you ever been retained in a case involving cosmetic products? A. No. Q. Your curriculum vitae that we marked as Exhibit 3, is it correct and up to date? A. It was up to date at the time

15 (Pages 54 to 57)

	Page 58		Page 60
1	or corrections need to be made to your CV,	1	is that right?
2	Exhibit 3, to bring it up to date?	2	A. Yes.
3	A. Well, I've terminated a	3	Q. What percentage of your time is
4	relationship with the University of Texas	4	spent in the clinical practice of medicine?
5	Medical Branch in Galveston where I was	5	A. Currently I see patients
6	their the medical director of their	6	one-half day a week and work as a supervisor
7	Employee Health Services Clinic. I continue	7	of the occupational medicine residents for
8	to be serve as an assistant clinical	8	additional time during the week, so clinical
9	professor of preventive medicine and family	9	activities would be about probably 12 hours a
10	medicine at that institution.	10	week.
11	I have terminated my	11	Q. Do you see or treat women for
12	relationship with the Enbridge Corporation as	12	gynecologic cancer?
13	their medical director.	13	A. I do not.
14	The Spectra Energy entry, which	14	Q. You have never worked for a
15	is about the seventh on the list of	15	company that manufactures cosmetic products,
16	professional activities, is also terminated	16	correct?
17	as that was a company that was merged and	17	A. That's correct.
18	became Enbridge.	18	Q. You're not a gynecologist or an
19	Q. Any other corrections or	19	oncologist, correct?
20	updates to your curriculum vitae that we've	20	A. That's correct.
21	marked as Exhibit 3?	21	Q. You're not a cancer biologist?
22	A. No.	22	MS. O'DELL: Object to the
23	Q. Why are you no longer serving	23	form.
24	as medical director, Employee Health Services	24	A. That's correct.
	Page 59		Page 61
1	with the University of Texas?	1	DVMD ZELLEDG
			BY MR. ZELLERS:
2	MS. O'DELL: Objection to form.	2	
2			
	MS. O'DELL: Objection to form.	2	Q. You are not a geologist,
3	MS. O'DELL: Objection to form.A. That was a contract that I had	2 3	Q. You are not a geologist, mineralogist or microscopist?
3 4	MS. O'DELL: Objection to form. A. That was a contract that I had through the University of Texas Houston	2 3 4	Q. You are not a geologist,mineralogist or microscopist?A. That's correct.
3 4 5	MS. O'DELL: Objection to form. A. That was a contract that I had through the University of Texas Houston College of Nursing that provided those	2 3 4 5	Q. You are not a geologist,mineralogist or microscopist?A. That's correct.Q. You're not an epidemiologist?
3 4 5 6	MS. O'DELL: Objection to form. A. That was a contract that I had through the University of Texas Houston College of Nursing that provided those services to UTMB, and UTMB decided to make a	2 3 4 5 6	 Q. You are not a geologist, mineralogist or microscopist? A. That's correct. Q. You're not an epidemiologist? A. Well, I may be considered an
3 4 5 6 7	MS. O'DELL: Objection to form. A. That was a contract that I had through the University of Texas Houston College of Nursing that provided those services to UTMB, and UTMB decided to make a change and go with another contractor.	2 3 4 5 6 7	 Q. You are not a geologist, mineralogist or microscopist? A. That's correct. Q. You're not an epidemiologist? A. Well, I may be considered an epidemiologist simply by my appointment as an
3 4 5 6 7 8	MS. O'DELL: Objection to form. A. That was a contract that I had through the University of Texas Houston College of Nursing that provided those services to UTMB, and UTMB decided to make a change and go with another contractor. BY MR. ZELLERS:	2 3 4 5 6 7 8	 Q. You are not a geologist, mineralogist or microscopist? A. That's correct. Q. You're not an epidemiologist? A. Well, I may be considered an epidemiologist simply by my appointment as an associate professor in the Department of
3 4 5 6 7 8 9	MS. O'DELL: Objection to form. A. That was a contract that I had through the University of Texas Houston College of Nursing that provided those services to UTMB, and UTMB decided to make a change and go with another contractor. BY MR. ZELLERS: Q. Why are you no longer serving	2 3 4 5 6 7 8	 Q. You are not a geologist, mineralogist or microscopist? A. That's correct. Q. You're not an epidemiologist? A. Well, I may be considered an epidemiologist simply by my appointment as an associate professor in the Department of Epidemiology at the School of Public Health
3 4 5 6 7 8 9	MS. O'DELL: Objection to form. A. That was a contract that I had through the University of Texas Houston College of Nursing that provided those services to UTMB, and UTMB decided to make a change and go with another contractor. BY MR. ZELLERS: Q. Why are you no longer serving as medical director for Spectra Energy	2 3 4 5 6 7 8 9	 Q. You are not a geologist, mineralogist or microscopist? A. That's correct. Q. You're not an epidemiologist? A. Well, I may be considered an epidemiologist simply by my appointment as an associate professor in the Department of Epidemiology at the School of Public Health here in Houston.
3 4 5 6 7 8 9 10 11	MS. O'DELL: Objection to form. A. That was a contract that I had through the University of Texas Houston College of Nursing that provided those services to UTMB, and UTMB decided to make a change and go with another contractor. BY MR. ZELLERS: Q. Why are you no longer serving as medical director for Spectra Energy Corporation and Enbridge Corporation?	2 3 4 5 6 7 8 9 10	 Q. You are not a geologist, mineralogist or microscopist? A. That's correct. Q. You're not an epidemiologist? A. Well, I may be considered an epidemiologist simply by my appointment as an associate professor in the Department of Epidemiology at the School of Public Health here in Houston. Q. Do you have any professional
3 4 5 6 7 8 9 10 11 12	MS. O'DELL: Objection to form. A. That was a contract that I had through the University of Texas Houston College of Nursing that provided those services to UTMB, and UTMB decided to make a change and go with another contractor. BY MR. ZELLERS: Q. Why are you no longer serving as medical director for Spectra Energy Corporation and Enbridge Corporation? A. Well, Spectra Energy no longer	2 3 4 5 6 7 8 9 10 11	 Q. You are not a geologist, mineralogist or microscopist? A. That's correct. Q. You're not an epidemiologist? A. Well, I may be considered an epidemiologist simply by my appointment as an associate professor in the Department of Epidemiology at the School of Public Health here in Houston. Q. Do you have any professional education in the field well, strike that.
3 4 5 6 7 8 9 10 11 12 13	MS. O'DELL: Objection to form. A. That was a contract that I had through the University of Texas Houston College of Nursing that provided those services to UTMB, and UTMB decided to make a change and go with another contractor. BY MR. ZELLERS: Q. Why are you no longer serving as medical director for Spectra Energy Corporation and Enbridge Corporation? A. Well, Spectra Energy no longer exists; it became Enbridge Corporation. And	2 3 4 5 6 7 8 9 10 11 12 13	 Q. You are not a geologist, mineralogist or microscopist? A. That's correct. Q. You're not an epidemiologist? A. Well, I may be considered an epidemiologist simply by my appointment as an associate professor in the Department of Epidemiology at the School of Public Health here in Houston. Q. Do you have any professional education in the field well, strike that. Have you ever published or
3 4 5 6 7 8 9 10 11 12 13 14	MS. O'DELL: Objection to form. A. That was a contract that I had through the University of Texas Houston College of Nursing that provided those services to UTMB, and UTMB decided to make a change and go with another contractor. BY MR. ZELLERS: Q. Why are you no longer serving as medical director for Spectra Energy Corporation and Enbridge Corporation? A. Well, Spectra Energy no longer exists; it became Enbridge Corporation. And in October of 2018, I determined that I did	2 3 4 5 6 7 8 9 10 11 12 13	 Q. You are not a geologist, mineralogist or microscopist? A. That's correct. Q. You're not an epidemiologist? A. Well, I may be considered an epidemiologist simply by my appointment as an associate professor in the Department of Epidemiology at the School of Public Health here in Houston. Q. Do you have any professional education in the field well, strike that. Have you ever published or conducted a meta-analysis?
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3 4 5 6 7 8 9 10 11 12 13 14 15	MS. O'DELL: Objection to form. A. That was a contract that I had through the University of Texas Houston College of Nursing that provided those services to UTMB, and UTMB decided to make a change and go with another contractor. BY MR. ZELLERS: Q. Why are you no longer serving as medical director for Spectra Energy Corporation and Enbridge Corporation? A. Well, Spectra Energy no longer exists; it became Enbridge Corporation. And in October of 2018, I determined that I did not I no longer had sufficient time to provide that service.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	 Q. You are not a geologist, mineralogist or microscopist? A. That's correct. Q. You're not an epidemiologist? A. Well, I may be considered an epidemiologist simply by my appointment as an associate professor in the Department of Epidemiology at the School of Public Health here in Houston. Q. Do you have any professional education in the field well, strike that. Have you ever published or conducted a meta-analysis? A. I have conducted meta-analyses. I've not published them.
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3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	MS. O'DELL: Objection to form. A. That was a contract that I had through the University of Texas Houston College of Nursing that provided those services to UTMB, and UTMB decided to make a change and go with another contractor. BY MR. ZELLERS: Q. Why are you no longer serving as medical director for Spectra Energy Corporation and Enbridge Corporation? A. Well, Spectra Energy no longer exists; it became Enbridge Corporation. And in October of 2018, I determined that I did not I no longer had sufficient time to provide that service. Q. Your undergraduate degree was in biologic sciences with a concentration in engineering; is that right?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	Q. You are not a geologist, mineralogist or microscopist? A. That's correct. Q. You're not an epidemiologist? A. Well, I may be considered an epidemiologist simply by my appointment as an associate professor in the Department of Epidemiology at the School of Public Health here in Houston. Q. Do you have any professional education in the field well, strike that. Have you ever published or conducted a meta-analysis? A. I have conducted meta-analyses. I've not published them. Q. You did not do any type of fellowship in epidemiology, correct? A. That's correct.
3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	MS. O'DELL: Objection to form. A. That was a contract that I had through the University of Texas Houston College of Nursing that provided those services to UTMB, and UTMB decided to make a change and go with another contractor. BY MR. ZELLERS: Q. Why are you no longer serving as medical director for Spectra Energy Corporation and Enbridge Corporation? A. Well, Spectra Energy no longer exists; it became Enbridge Corporation. And in October of 2018, I determined that I did not I no longer had sufficient time to provide that service. Q. Your undergraduate degree was in biologic sciences with a concentration in engineering; is that right? A. Yes.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	Q. You are not a geologist, mineralogist or microscopist? A. That's correct. Q. You're not an epidemiologist? A. Well, I may be considered an epidemiologist simply by my appointment as an associate professor in the Department of Epidemiology at the School of Public Health here in Houston. Q. Do you have any professional education in the field well, strike that. Have you ever published or conducted a meta-analysis? A. I have conducted meta-analyses. I've not published them. Q. You did not do any type of fellowship in epidemiology, correct? A. That's correct. Q. You're not board certified in
3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	MS. O'DELL: Objection to form. A. That was a contract that I had through the University of Texas Houston College of Nursing that provided those services to UTMB, and UTMB decided to make a change and go with another contractor. BY MR. ZELLERS: Q. Why are you no longer serving as medical director for Spectra Energy Corporation and Enbridge Corporation? A. Well, Spectra Energy no longer exists; it became Enbridge Corporation. And in October of 2018, I determined that I did not I no longer had sufficient time to provide that service. Q. Your undergraduate degree was in biologic sciences with a concentration in engineering; is that right? A. Yes. Q. You received a Ph.D. in	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Q. You are not a geologist, mineralogist or microscopist? A. That's correct. Q. You're not an epidemiologist? A. Well, I may be considered an epidemiologist simply by my appointment as an associate professor in the Department of Epidemiology at the School of Public Health here in Houston. Q. Do you have any professional education in the field well, strike that. Have you ever published or conducted a meta-analysis? A. I have conducted meta-analyses. I've not published them. Q. You did not do any type of fellowship in epidemiology, correct? A. That's correct. Q. You're not board certified in epidemiology; is that right?

16 (Pages 58 to 61)

		1	
	Page 62		Page 64
1	a pulmonologist?	1	A. I think I had opinions about
2	A. That's correct.	2	talcum powder and its constituents, but if
3	Q. You're not a material	3	you could be more specific, I might be able
4	scientist?	4	to give you a more specific answer.
5	A. That's correct.	5	BY MR. ZELLERS:
6	Q. Nor are you a pathologist?	6	Q. Did you ever, before getting
7	A. Correct.	7	involved in this litigation in October of
8	Q. You've never been involved in	8	2018, do research strike that.
9	any pathological exam or research relating to	9	You've never published on
10	ovarian cancer; is that right?	10	talcum powder, correct?
11	MS. O'DELL: Object to the	11	A. That's correct.
12	form.	12	Q. You have never published on the
13	A. I'm not sure exactly what you	13	constituent components of talcum powder,
14	mean by your question.	14	correct?
15	BY MR. ZELLERS:	15	A. That may not be the case. I've
16	Q. Sure. Let me withdraw that.	16	done work in some other minerals which have
17	You've never been involved in	17	resulted in publications, for example,
18	terms of the research relating to ovarian	18	vermiculite, which have touched on the issues
19	cancer, correct?	19	of asbestos, association with talc,
20	A. Not specifically, no.	20	association with other minerals, but never
21	Q. You've never authored any	21	specifically regarding talc.
22	literature or publications relating to talcum	22	Q. Are those publications on your
23	powder?	23	CV?
24	A. No.	24	A. They are.
			•
	Page 63		Page 65
1	Q. Or relating to ovarian cancer,	1	Q. That we marked as Exhibit 3?
2	correct?	2	A. Yes.
3	A. No.	3	Q. Okay. Have you ever
4	Q. Okay. What journals well,	4	communicated with the FDA regarding talcum
5	strike that.	5	powder?
6	You have never published on	6	A. I've not.
7	fragrance chemicals; is that right?	7	Q. Have you ever communicated with
8	MS. O'DELL: Object to the	8	Health Canada regarding talcum powder?
9	form.	9	A. No.
10	A. That's correct.	10	Q. When did you first start
11	BY MR. ZELLERS:	11	preparing your report which we've marked as
12	Q. Never done any research on	12	Exhibit 2?
13	fragrance chemicals, correct?	13	A. Well, I began a literature
14	A. I've done some work with	14	review immediately after talking to
15	fragrance chemicals and health effects that	15	Mr. Abney.
16	are associated with them, but I have not I	16	Q. My question, I guess, is: When
17	would not classify that as research or	17	did you start writing your report?
18	publication.	18	A. Well, technically I started
19	Q. You had no opinions regarding	19	writing my report after I was retained by
20	talcum powder or any of its constituent	20	plaintiffs' counsel.
21	components before getting involved in this	21	Q. Late October, early
22	litigation; is that right?	22	November 2018?
23	MS. O'DELL: Object to the	23	MS. O'DELL: Object to the
24	form.	24	form, misstates his prior testimony.

17 (Pages 62 to 65)

	Arch 1. "Chip" Ca	ar som	, M.D., PII.D.
	Page 66		Page 68
1	A. In October of 2018.	1	and bolts of what goes on legally in this
2	BY MR. ZELLERS:	2	case. I know there are multiple lawsuits,
3	Q. Have you reviewed any of the	3	and I'm not sure which ones those these
4	deposition transcripts of any of the experts	4	are pertinent to.
5	that have been deposed in this litigation?	5	BY MR. ZELLERS:
6	A. Yes.	6	Q. My question is a little
7	Q. What deposition transcripts of	7	different and I hope pretty simple: In
8	experts have you reviewed?	8	addition to the depositions, transcripts and
9	A. Oh, of experts? No, I have not	9	reports that you have listed on pages 27 and
10	reviewed well, I've reviewed I've	10	28 of Exhibit 4, your literature list, are
11	reviewed expert depositions, but I don't know	11	there any additional depositions or
12	what case they were deposed in, but it	12	transcripts that you've reviewed?
13	relates to talcum powder and ovarian cancer	13	A. Pardon me for a moment while I
14	issue.	14	review this.
15	Q. What expert depositions have	15	(Document review.)
16	you reviewed?	16	A. No, I'm not aware that there
17	A. They're all cited in the	17	are.
18	literature exhibit.	18	BY MR. ZELLERS:
19	Q. All of the deposition	19	Q. Your testimony earlier was that
20	transcripts that you've reviewed are cited in	20	you have reviewed each of those depositions
21	Exhibit 4?	21	in their entirety; is that right?
22	A. I think any of the transcripts	22	A. Yes.
23	that I review are reviewed are probably	23	Q. You have also reviewed the
24	included in here.	24	exhibits to those depositions; is that right?
	Page 67		Page 69
1	Q. Are you aware of reviewing any	1	A. If they were made available to
2	transcripts that you did not include in your	2	me, I've looked at all those exhibits as
3	literature statement?	3	well.
4	A. I'm not aware, but I can't tell	4	Q. On page 27 of Exhibit 4, who is
5	you as I'm sitting here right now whether all	5	Annie Yessaian?
6	of those are included in this literature	6	A. On page 24?
7	statement or not.	7	Q. Strike that. I'm sorry. On
8	Q. You looking at page	8	page 27 of Exhibit 4
9	MS. O'DELL: I'm sorry. Go	9	A. I see.
10	ahead.	10	Q at the bottom, who is Annie
11	BY MR. ZELLERS:	11	Yessaian?
12	Q. Are there any that you believe	12	A. I don't recall.
13	you have reviewed that are not included in	13	Q. You reviewed her entire
14	the literature statement?	14	transcript and you don't recall who she is?
15	A. Well, let me just see here.	15	A. I don't.
16	There are	16	Q. Well, go to the next page. Who
17	MS. O'DELL: I think they're at	17	is Pat Downey?
18	the end, Dr. Carson.	18	A. I believe Pat Downey is an
19	THE WITNESS: At the very end.	19	operative of the Imerys company.
20	A. Beginning on page 27 is a list	20	Q. Do you know what Mr. Downey's
21	of the depositions, transcripts and reports	21	position is?
22	that I've reviewed, which include some of the	22	A. It's a supervisory position
23	expert witnesses, but again, I would have to	23	regarding regarding quality of the talc
24	say I'm I'm sort of unaware of the nuts	24	product.
24	say I'm I'm sort of unaware of the nuts	24	product.

18 (Pages 66 to 69)

	Page 70		Page 72
1	Q. Who is John Hopkins?	1	BY MR. ZELLERS:
2	A. John Hopkins is an official, I	2	Q. Once you looked at these
3	believe, of I'm not sure of Johnson &	3	documents, the Imerys documents and the
4	Johnson, I believe, who has some oversight of	4	documents produced by the Johnson & Johnson
5	talc quality as well.	5	companies, did you ask plaintiffs' counsel
6	Q. Susan Nicholson, who is she?	6	for any additional documents?
7	A. I don't recall.	7	A. I did not. My understanding is
8	Q. Who is Julie Pier?	8	that most of these are reports, testing
9	A. Julie Pier is another scientist	9	reports, and most of them are positive
10	who works for Imerys, who is responsible for	10	results regarding the presence of asbestos or
11	* · · · · · · · · · · · · · · · · · · ·	11	fibers in the product. And I know that there
	testing and quality.	12	-
12	Q. In your clinical and academic		were many others that may not have shown
13	practice, do you typically rely upon	13	positive results that I did not look at.
14	depositions of company witnesses or experts?	14	Q. Did you ask the plaintiff
15	MS. O'DELL: Object to the	15	attorneys to show you or provide you with the
16	form.	16	testing documentation that showed an absence
17	A. If there's pertinent	17	of asbestos or asbestos fibers in the talcum
18	information in there that leads me to other	18	powder?
19	areas or helps me formulate my opinions, then	19	A. Regarding the test results that
20	yes.	20	are equivalent to these that were negative,
21	BY MR. ZELLERS:	21	no, I did not request those.
22	Q. In the papers and publications	22	Q. Did you review documents
23	that you have identified in your curriculum	23	relating to any fragrance chemicals that are
24	vitae, Exhibit 3, do you ever recall citing	24	contained in or that you believe are
	Page 71		Page 73
1	to company witness deposition testimony?	1	contained in the talcum powder?
2	A. I don't typically cite	2	A. Yes. I did review some lists
3	deposition testimonies in published papers.	3	and, of course, Dr. Crowley's report.
4	Q. You cite to various company	4	Q. Do you have any idea or
5	documents. This is on pages 29 to 30 of	5	understanding as to the amount or amounts of
6	Exhibit 4, your list of literature; is that	6	the fragrance chemicals that are contained in
7	right?	7	the talcum powder in either the Johnson &
8	A. Yes.	8	Johnson Consumer company talcum powder that's
9	Q. Did you rely on these documents	9	involved in this litigation?
10	in formulating your opinions?	10	MS. O'DELL: Object to the
			2
	A Yes	1 11	form
11	A. Yes. O Were these documents selected	11 12	form. MR. ZELLERS: Let me withdraw
11 12	Q. Were these documents selected	12	MR. ZELLERS: Let me withdraw
11 12 13	Q. Were these documents selected for you by plaintiffs' counsel?	12 13	MR. ZELLERS: Let me withdraw that.
11 12 13 14	Q. Were these documents selected for you by plaintiffs' counsel? A. Yes, they were.	12 13 14	MR. ZELLERS: Let me withdraw that. BY MR. ZELLERS:
11 12 13 14 15	Q. Were these documents selected for you by plaintiffs' counsel?A. Yes, they were.Q. Are you able to identify what	12 13 14 15	MR. ZELLERS: Let me withdraw that. BY MR. ZELLERS: Q. Do you know or have any
11 12 13 14 15 16	Q. Were these documents selected for you by plaintiffs' counsel?A. Yes, they were.Q. Are you able to identify what each of the documents are?	12 13 14 15 16	MR. ZELLERS: Let me withdraw that. BY MR. ZELLERS: Q. Do you know or have any understanding as to the amounts of fragrance
11 12 13 14 15 16 17	Q. Were these documents selected for you by plaintiffs' counsel? A. Yes, they were. Q. Are you able to identify what each of the documents are? MS. O'DELL: Based on the Bates	12 13 14 15 16 17	MR. ZELLERS: Let me withdraw that. BY MR. ZELLERS: Q. Do you know or have any understanding as to the amounts of fragrance chemicals that are in the talcum powder?
11 12 13 14 15 16 17	Q. Were these documents selected for you by plaintiffs' counsel? A. Yes, they were. Q. Are you able to identify what each of the documents are? MS. O'DELL: Based on the Bates number?	12 13 14 15 16 17 18	MR. ZELLERS: Let me withdraw that. BY MR. ZELLERS: Q. Do you know or have any understanding as to the amounts of fragrance chemicals that are in the talcum powder? A. I do not have the specific
11 12 13 14 15 16 17 18	Q. Were these documents selected for you by plaintiffs' counsel? A. Yes, they were. Q. Are you able to identify what each of the documents are? MS. O'DELL: Based on the Bates number? MR. ZELLERS: Based on the	12 13 14 15 16 17 18 19	MR. ZELLERS: Let me withdraw that. BY MR. ZELLERS: Q. Do you know or have any understanding as to the amounts of fragrance chemicals that are in the talcum powder? A. I do not have the specific formulation or quantities of those substances
11 12 13 14 15 16 17 18 19 20	Q. Were these documents selected for you by plaintiffs' counsel? A. Yes, they were. Q. Are you able to identify what each of the documents are? MS. O'DELL: Based on the Bates number? MR. ZELLERS: Based on the Bates numbers.	12 13 14 15 16 17 18 19 20	MR. ZELLERS: Let me withdraw that. BY MR. ZELLERS: Q. Do you know or have any understanding as to the amounts of fragrance chemicals that are in the talcum powder? A. I do not have the specific formulation or quantities of those substances that contributed to the products.
11 12 13 14 15 16 17 18 19 20 21	Q. Were these documents selected for you by plaintiffs' counsel? A. Yes, they were. Q. Are you able to identify what each of the documents are? MS. O'DELL: Based on the Bates number? MR. ZELLERS: Based on the Bates numbers. A. No, I am not. I would have to	12 13 14 15 16 17 18 19 20 21	MR. ZELLERS: Let me withdraw that. BY MR. ZELLERS: Q. Do you know or have any understanding as to the amounts of fragrance chemicals that are in the talcum powder? A. I do not have the specific formulation or quantities of those substances that contributed to the products. Q. Do
11 12 13 14 15 16 17 18 19 20 21 22	Q. Were these documents selected for you by plaintiffs' counsel? A. Yes, they were. Q. Are you able to identify what each of the documents are? MS. O'DELL: Based on the Bates number? MR. ZELLERS: Based on the Bates numbers. A. No, I am not. I would have to look at each individual document to refresh	12 13 14 15 16 17 18 19 20 21	MR. ZELLERS: Let me withdraw that. BY MR. ZELLERS: Q. Do you know or have any understanding as to the amounts of fragrance chemicals that are in the talcum powder? A. I do not have the specific formulation or quantities of those substances that contributed to the products. Q. Do MS. O'DELL: Excuse me.
11 12 13 14 15 16 17 18 19 20 21	Q. Were these documents selected for you by plaintiffs' counsel? A. Yes, they were. Q. Are you able to identify what each of the documents are? MS. O'DELL: Based on the Bates number? MR. ZELLERS: Based on the Bates numbers. A. No, I am not. I would have to	12 13 14 15 16 17 18 19 20 21	MR. ZELLERS: Let me withdraw that. BY MR. ZELLERS: Q. Do you know or have any understanding as to the amounts of fragrance chemicals that are in the talcum powder? A. I do not have the specific formulation or quantities of those substances that contributed to the products. Q. Do

19 (Pages 70 to 73)

Arch I. "Chip" Carson, M.D., Ph.D.

	Page 74		Page 76
1	finish.	1	understanding of business practices and these
2	MS. O'DELL: In that instance,	2	types of industries, I've reviewed an
3	I don't know that he was, and so if he	3	extremely small percentage of those.
4	was, my apologies.	4	Q. Is it your practice in your
5	MR. ZELLERS: It's okay.	5	academic work or your clinical research work
6	MS. O'DELL: I've been on my	6	to rely on internal company documents?
7	best behavior today, as you know,	7	A. Yes, it is.
8	so but I don't want the witness to	8	Q. Do you rely on internal company
9	feel as if they're being cut off, and	9	documents when you publish papers?
10	because Dr. Carson is a very polite	10	A. In some cases.
11	gentlemen, he would let you interrupt	11	Q. Can you tell me in what cases
12	him.	12	or instances you have relied on internal
13	MR. ZELLERS: Of course.	13	company documents in your publications?
14	MS. O'DELL: And I don't think	14	A. Well, for example, I did I
15	that's fair.	15	was involved in some research work in
16	So, Dr. Carson, if you're	16	conjunction with NIOSH at the O.M. Scott
17	finished, great. If you're not, you	17	Company at Marysville, Ohio, where we did
18	may continue.	18	a we performed a research in the company
19	A. Well, I was going to say that	19	and relied on some internal documents in
20	my opinion is that there are very small	20	terms of gauging concentrations, industrial
21	quantities of those substances that	21	hygiene records and so forth, in order to
22	contribute to the fragrance component.	22	draw conclusions that were pertinent to those
23	BY MR. ZELLERS:	23	publications.
24	Q. Do you know how those	24	Q. Was that data or were those
	Q. Bo you know how those		Q. Was that data of were those
	Page 75		Page 77
1		1	
1 2	Page 75 quantities of fragrance chemicals may have changed over the years?	1 2	Page 77 internal communications that you relied on? A. They were both.
	quantities of fragrance chemicals may have		internal communications that you relied on?
2	quantities of fragrance chemicals may have changed over the years?	2	internal communications that you relied on? A. They were both.
2	quantities of fragrance chemicals may have changed over the years? A. My understanding is they have	2	internal communications that you relied on? A. They were both. Q. What is the publication on your
2 3 4	quantities of fragrance chemicals may have changed over the years? A. My understanding is they have not changed dramatically, but there have been	2 3 4	internal communications that you relied on? A. They were both. Q. What is the publication on your CV where you relied on those materials?
2 3 4 5	quantities of fragrance chemicals may have changed over the years? A. My understanding is they have not changed dramatically, but there have been certain substitutions over time.	2 3 4 5	internal communications that you relied on? A. They were both. Q. What is the publication on your CV where you relied on those materials? A. Well, let me see here. I think
2 3 4 5 6	quantities of fragrance chemicals may have changed over the years? A. My understanding is they have not changed dramatically, but there have been certain substitutions over time. Q. Do you agree that to the extent	2 3 4 5 6	internal communications that you relied on? A. They were both. Q. What is the publication on your CV where you relied on those materials? A. Well, let me see here. I think the first author looking back here the
2 3 4 5 6 7	quantities of fragrance chemicals may have changed over the years? A. My understanding is they have not changed dramatically, but there have been certain substitutions over time. Q. Do you agree that to the extent that you have reviewed internal documents,	2 3 4 5 6 7	internal communications that you relied on? A. They were both. Q. What is the publication on your CV where you relied on those materials? A. Well, let me see here. I think the first author looking back here the first author would be Jim Lockey. Q. Looking at page 6? A. It's on page 6, and the
2 3 4 5 6 7 8	quantities of fragrance chemicals may have changed over the years? A. My understanding is they have not changed dramatically, but there have been certain substitutions over time. Q. Do you agree that to the extent that you have reviewed internal documents, either of Imerys or from Johnson & Johnson	2 3 4 5 6 7 8	internal communications that you relied on? A. They were both. Q. What is the publication on your CV where you relied on those materials? A. Well, let me see here. I think the first author looking back here the first author would be Jim Lockey. Q. Looking at page 6?
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	quantities of fragrance chemicals may have changed over the years? A. My understanding is they have not changed dramatically, but there have been certain substitutions over time. Q. Do you agree that to the extent that you have reviewed internal documents, either of Imerys or from Johnson & Johnson companies, that you have only reviewed the documents that were hand-selected by the plaintiff lawyers for you to review? MS. O'DELL: Object to the form. A. I agree that the only documents that I've reviewed regarding the internal products of Johnson & Johnson or Imerys are the ones that were provided by the plaintiffs' attorneys. BY MR. ZELLERS: Q. Do you know what percentage of	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	internal communications that you relied on? A. They were both. Q. What is the publication on your CV where you relied on those materials? A. Well, let me see here. I think the first author looking back here the first author would be Jim Lockey. Q. Looking at page 6? A. It's on page 6, and the there are two publications there. One is Pulmonary Changes After Exposure to Vermiculite Contaminated With Fibrous Tremolite that appeared in the American Review of Respiratory Disease in 1984. There's another publication which is a book chapter called Pulmonary Hazards From Vermiculite that appeared in a book titled Health Issues Related to Metal and Nonmetallic Mining. Q. Do you agree that when you have
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	quantities of fragrance chemicals may have changed over the years? A. My understanding is they have not changed dramatically, but there have been certain substitutions over time. Q. Do you agree that to the extent that you have reviewed internal documents, either of Imerys or from Johnson & Johnson companies, that you have only reviewed the documents that were hand-selected by the plaintiff lawyers for you to review? MS. O'DELL: Object to the form. A. I agree that the only documents that I've reviewed regarding the internal products of Johnson & Johnson or Imerys are the ones that were provided by the plaintiffs' attorneys. BY MR. ZELLERS: Q. Do you know what percentage of the documents that have been produced in this	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	internal communications that you relied on? A. They were both. Q. What is the publication on your CV where you relied on those materials? A. Well, let me see here. I think the first author looking back here the first author would be Jim Lockey. Q. Looking at page 6? A. It's on page 6, and the there are two publications there. One is Pulmonary Changes After Exposure to Vermiculite Contaminated With Fibrous Tremolite that appeared in the American Review of Respiratory Disease in 1984. There's another publication which is a book chapter called Pulmonary Hazards From Vermiculite that appeared in a book titled Health Issues Related to Metal and Nonmetallic Mining. Q. Do you agree that when you have been provided only a small subset of the
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	quantities of fragrance chemicals may have changed over the years? A. My understanding is they have not changed dramatically, but there have been certain substitutions over time. Q. Do you agree that to the extent that you have reviewed internal documents, either of Imerys or from Johnson & Johnson companies, that you have only reviewed the documents that were hand-selected by the plaintiff lawyers for you to review? MS. O'DELL: Object to the form. A. I agree that the only documents that I've reviewed regarding the internal products of Johnson & Johnson or Imerys are the ones that were provided by the plaintiffs' attorneys. BY MR. ZELLERS: Q. Do you know what percentage of the documents that have been produced in this litigation by the Johnson & Johnson companies	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	internal communications that you relied on? A. They were both. Q. What is the publication on your CV where you relied on those materials? A. Well, let me see here. I think the first author looking back here the first author would be Jim Lockey. Q. Looking at page 6? A. It's on page 6, and the there are two publications there. One is Pulmonary Changes After Exposure to Vermiculite Contaminated With Fibrous Tremolite that appeared in the American Review of Respiratory Disease in 1984. There's another publication which is a book chapter called Pulmonary Hazards From Vermiculite that appeared in a book titled Health Issues Related to Metal and Nonmetallic Mining. Q. Do you agree that when you have been provided only a small subset of the documents of a company relating to a

20 (Pages 74 to 77)

<u></u>	Page 78		Page 80
1	MS. O'DELL: Object to the	1	department?
2	form.	2	A. She's in my department, yes.
3	A. I don't agree that that's the	3	Q. You understand she's a
4	case because I am capable of understanding	4	lawyer strike that.
5	that it's a subset of available information,	5	You understand she's an expert
6	and I can make a reliable determination on	6	for the plaintiffs in this litigation?
7	the pertinence of that material regardless.	7	A. I didn't know that.
8	BY MR. ZELLERS:	8	Q. Dr. Ness never told you that
9	Q. Without looking at any other	9	she was an expert witness for plaintiffs in
10	documents or any documents that may put the	10	this matter?
11	documents you were provided in context?	11	A. No, we didn't discuss this
12	MS. O'DELL: Object to the	12	case. We only discussed the issue.
13	form.	13	Q. Any other colleagues that you
14	A. It depends on the specific	14	discussed your report and opinions with?
15	case, but I would say in most cases, yes.	15	MS. O'DELL: Object to the
16	BY MR. ZELLERS:	16	form.
17	Q. In this case, it was not	17	
18		18	A. I think I shared some of my
	necessary for you to look at any documents other than those specific documents the	1	thinking with the occupational medicine
19	*	19	residents as a group and asked them to
20	plaintiffs provided to you; is that your	20	consider certain issues in the case.
21	testimony?	21	BY MR. ZELLERS:
22	MS. O'DELL: Object to the	22	Q. Did they contribute to your
23	form.	23	review and analysis and opinions?
24	A. Regarding the contribution to	24	A. We had an interesting
	Page 79		Page 81
1	my opinions, I would say, yes, it was not	1	discussion, but I don't think that changed my
2	necessary.	2	opinions in any way.
3	BY MR. ZELLERS:	3	Q. The opinions that you're
4	Q. Did you do any independent	4	expressing in this case are your opinions; is
5	investigation to reach your opinions, other	5	that right?
6	than the literature search and review of	6	A. That's correct.
7	websites that you told us about earlier?	7	Q. Your opinions you set forth in
8	A. Other than just general	8	your report beginning on page 7; is that
9	discussion with colleagues, no.	9	right?
10	Q. Did any of the colleagues that	10	A. Let me refer to my report, if
11	you spoke with provide you with any	11	you don't mind.
12	substantive support for your opinions?	12	MS. O'DELL: Object to the
13	A. Not that I can recall. It was	13	form.
14	mostly just helpful feedback.	14	A. I would say I would say in
15	Q. The colleagues that you spoke	15	answer to that question that, yes, my
16	with were who?	16	opinions do begin on page 7 of the report.
	A. Various colleagues in my	17	BY MR. ZELLERS:
17		18	Q. Your first opinion set forth on
17		1 10	
17 18	department or in the School of Public Health.	1	
17 18 19	department or in the School of Public Health. Q. Who?	19	page 7 is that talcum powder is immunogenic
17 18 19 20	department or in the School of Public Health. Q. Who? A. Well, Dr. George Delclos, who	19 20	page 7 is that talcum powder is immunogenic and carcinogenic; is that right?
17 18 19 20 21	department or in the School of Public Health. Q. Who? A. Well, Dr. George Delclos, who is a pulmonologist; Dr. Brett Perkison, who	19 20 21	page 7 is that talcum powder is immunogenic and carcinogenic; is that right? A. Yes.
17 18 19 20 21 22	department or in the School of Public Health. Q. Who? A. Well, Dr. George Delclos, who is a pulmonologist; Dr. Brett Perkison, who is an occupational medicine physician;	19 20 21 22	page 7 is that talcum powder is immunogenic and carcinogenic; is that right? A. Yes. MS. O'DELL: Excuse me.
17 18 19 20 21	department or in the School of Public Health. Q. Who? A. Well, Dr. George Delclos, who is a pulmonologist; Dr. Brett Perkison, who	19 20 21	page 7 is that talcum powder is immunogenic and carcinogenic; is that right? A. Yes.

21 (Pages 78 to 81)

		1	
	Page 82		Page 84
1	perineal use of talcum powder results in	1	MS. O'DELL: Object to the
2	direct exposure to the ovaries either via	2	form.
3	inhalation or migration through the female	3	A. It's an anatomical fact. The
4	reproductive tract, correct?	4	physiology of the reproductive system does
5	A. I would not phrase the opinion	5	not provide the ovaries with the kind of
6	in that way, but in general, that is my	6	clearance system that, for example, the lungs
7	opinion, yes.	7	would have for inhaled exposures.
8	Q. How would you phrase your	8	BY MR. ZELLERS:
9	second opinion?	9	Q. The words "no intrinsic
10	A. I think my second opinion	10	elimination system," are those your words or
11	relates mostly to the direct exposure to the	11	are those words that you've seen reported in
12	reproductive tract that perineal use of	12	another study or another paper?
13	talcum powder produces.	13	A. I think that's a fairly generic
14	Q. Are you opining as to	14	description, that those are my words.
15	inhalation as an exposure of talcum powder to	15	Q. Your fourth opinion is that you
16	women's ovaries?	16	believe that the epidemiological studies on
17	MS. O'DELL: Object to the	17	talcum powder and ovarian cancer show about a
18	form.	18	30% increased risk; is that right?
19	A. Only as a secondary route of	19	A. Correct.
20	exposure.	20	MS. O'DELL: Object to the
21	BY MR. ZELLERS:	21	form.
22	Q. Is it part of your opinions or	22	BY MR. ZELLERS:
23	do you defer to other experts on inhalation?	23	Q. As you told us at the outset,
24	A. I would include that as my	24	those are all still your opinions, although
	Page 83		Page 85
1	opinion.	1	you do believe even stronger that there is a
2	Q. So you're testifying here today	2	causal association between talcum powder and
3	that the perineal use of talcum powder	3	ovarian cancer; is that right?
4	results in direct exposure to the ovaries	4	A. That's correct.
5	through migration through the female	5	Q. Have you published on your
6	reproductive tract and that inhalation also	6	theory that baby powder causes ovarian
7	results in exposure of talcum powder to the	7	cancer?
8	ovaries; is that right?	8	A. No.
9	A. That is correct, but my basic	9	Q. Do you have plans to do that?
10	opinion is that perineal use of talcum powder	10	A. Not presently.
11	exposes the entire reproductive tract,	11	Q. Have you conducted any tests or
12	including the pelvic cavity. So it's a bit	12	experiments to confirm your theory that talc
13	more extensive than your phrasing.	13	migrates to the ovaries?
		13 14	migrates to the ovaries? MS. O'DELL: Object to the
13	more extensive than your phrasing.	14 15	MS. O'DELL: Object to the form.
13 14	more extensive than your phrasing. Q. Your third opinion is very similar to your first opinion, except that here you add that it's your opinion that the	14 15 16	MS. O'DELL: Object to the form. A. These are conclusions that I
13 14 15	more extensive than your phrasing. Q. Your third opinion is very similar to your first opinion, except that	14 15 16 17	MS. O'DELL: Object to the form. A. These are conclusions that I have drawn based on published literature. I
13 14 15 16	more extensive than your phrasing. Q. Your third opinion is very similar to your first opinion, except that here you add that it's your opinion that the ovaries are particularly susceptible to the carcinogenicity of talcum powder because they	14 15 16 17 18	MS. O'DELL: Object to the form. A. These are conclusions that I have drawn based on published literature. I wouldn't characterize them as a theory. I
13 14 15 16 17	more extensive than your phrasing. Q. Your third opinion is very similar to your first opinion, except that here you add that it's your opinion that the ovaries are particularly susceptible to the	14 15 16 17 18 19	MS. O'DELL: Object to the form. A. These are conclusions that I have drawn based on published literature. I wouldn't characterize them as a theory. I think they're pretty much established fact.
13 14 15 16 17 18	more extensive than your phrasing. Q. Your third opinion is very similar to your first opinion, except that here you add that it's your opinion that the ovaries are particularly susceptible to the carcinogenicity of talcum powder because they	14 15 16 17 18 19 20	MS. O'DELL: Object to the form. A. These are conclusions that I have drawn based on published literature. I wouldn't characterize them as a theory. I think they're pretty much established fact. BY MR. ZELLERS:
13 14 15 16 17 18	more extensive than your phrasing. Q. Your third opinion is very similar to your first opinion, except that here you add that it's your opinion that the ovaries are particularly susceptible to the carcinogenicity of talcum powder because they have, in your words, "no intrinsic	14 15 16 17 18 19 20 21	MS. O'DELL: Object to the form. A. These are conclusions that I have drawn based on published literature. I wouldn't characterize them as a theory. I think they're pretty much established fact. BY MR. ZELLERS: Q. I'm going to ask you about all
13 14 15 16 17 18 19 20	more extensive than your phrasing. Q. Your third opinion is very similar to your first opinion, except that here you add that it's your opinion that the ovaries are particularly susceptible to the carcinogenicity of talcum powder because they have, in your words, "no intrinsic elimination system"; is that right?	14 15 16 17 18 19 20 21 22	MS. O'DELL: Object to the form. A. These are conclusions that I have drawn based on published literature. I wouldn't characterize them as a theory. I think they're pretty much established fact. BY MR. ZELLERS: Q. I'm going to ask you about all these opinions, and so we'll go through the
13 14 15 16 17 18 19 20 21	more extensive than your phrasing. Q. Your third opinion is very similar to your first opinion, except that here you add that it's your opinion that the ovaries are particularly susceptible to the carcinogenicity of talcum powder because they have, in your words, "no intrinsic elimination system"; is that right? A. That's correct.	14 15 16 17 18 19 20 21	MS. O'DELL: Object to the form. A. These are conclusions that I have drawn based on published literature. I wouldn't characterize them as a theory. I think they're pretty much established fact. BY MR. ZELLERS: Q. I'm going to ask you about all

22 (Pages 82 to 85)

	Arch 1. "Chip" Ca		
	Page 86		Page 88
1	some of these matters are established fact.	1	you aware of any article that identifies
2	My question is: Did you do any	2	inflammation in a woman's reproductive tract
3	tests or experiments as part of your review	3	resulting from external genital talc
4	and analysis in this matter?	4	application?
5	A. I did not.	5	MS. O'DELL: Object to the
6	Q. Did you do any tests or	6	form.
7	experiments relating to your opinion that	7	A. I would say that the studies
8	talc causes cancer via inflammation?	8	which have looked at that have relied on the
9	A. I did not.	9	result of internal application to show
10	Q. Can you identify any article	10	migration. There have been studies that have
11	that identifies inflammation anywhere in a	11	shown inflammation as the result of talc, and
12	woman's reproductive tract that results from	12	in my opinion, external application is the
13	external genital tale application?	13	same as internal application in the
14	MS. O'DELL: Object to the	14	reproductive tract.
15	form.	15	BY MR. ZELLERS:
16	A. I think there are a number of	16	Q. I don't mean to be
17		17	•
18	published articles that allude to that	18	argumentative, and I don't want to be, but
	relationship and draw a fairly strong conclusion that it exists.	1	can you name me an article that identifies
19		19	inflammation in a woman's reproductive tract
20	MS. O'DELL: Mike, excuse me,	20	resulting from external genital talc
21	and I'm sorry to interrupt. We've	21	application?
22	been going over an hour and a half.	22	MS. O'DELL: Objection, asked
23	Are you at a point where we can take	23	and answered.
24	just a short break for	24	A. I can't specifically.
	Page 87		Page 89
1	MR. ZELLERS: Sure, we can.	1	MR. ZELLERS: Let's take a
2	Let me just ask these couple of	2	break.
3	questions, and then we'll take a	3	THE VIDEOGRAPHER: We're off
4	break.	4	the record, 10:37, end of Tape 1.
5	MS. O'DELL: Sure.	5	(Recess taken, 10:37 a.m. to
6	BY MR. ZELLERS:	6	10:55 a.m.)
7	Q. So please identify for me any	7	THE VIDEOGRAPHER: We're on the
8	articles that you have reviewed that identify	8	record at 10:55, beginning of Tape 2.
9	inflammation anywhere in a woman's	9	BY MR. ZELLERS:
10	reproductive tract resulting from external	10	Q. Dr. Carson, two of the things
11	genital talc application.	11	that you have reviewed since authoring your
12	MS. O'DELL: Objection to form.	12	report in November of 2018 that you believe
13	A. I think I think the research	13	support your conclusions in this matter and
	evidence that includes the epidemiology	14	your opinions in this matter are the draft
14			
14 15	piece, which is limited to external	1 15	screening assessment from Health Canada
15	piece, which is limited to external application of talcum powder, has significant	15 16	screening assessment from Health Canada, which we marked as Exhibit 9, and the Taher
15 16	application of talcum powder, has significant	16	which we marked as Exhibit 9, and the Taher
15 16 17	application of talcum powder, has significant enough correspondence with the biological	16 17	which we marked as Exhibit 9, and the Taher paper, which has been marked as Exhibit 7; is
15 16 17 18	application of talcum powder, has significant enough correspondence with the biological experimentation literature that it allows us	16 17 18	which we marked as Exhibit 9, and the Taher paper, which has been marked as Exhibit 7; is that right?
15 16 17 18 19	application of talcum powder, has significant enough correspondence with the biological experimentation literature that it allows us to draw those conclusions.	16 17 18 19	which we marked as Exhibit 9, and the Taher paper, which has been marked as Exhibit 7; is that right? A. Yes.
15 16 17 18 19 20	application of talcum powder, has significant enough correspondence with the biological experimentation literature that it allows us to draw those conclusions. BY MR. ZELLERS:	16 17 18 19 20	which we marked as Exhibit 9, and the Taher paper, which has been marked as Exhibit 7; is that right? A. Yes. Q. Have you looked into what other
15 16 17 18 19 20 21	application of talcum powder, has significant enough correspondence with the biological experimentation literature that it allows us to draw those conclusions. BY MR. ZELLERS: Q. I understand you've drawn some	16 17 18 19 20 21	which we marked as Exhibit 9, and the Taher paper, which has been marked as Exhibit 7; is that right? A. Yes. Q. Have you looked into what other public health authorities, other than
15 16 17 18 19 20 21	application of talcum powder, has significant enough correspondence with the biological experimentation literature that it allows us to draw those conclusions. BY MR. ZELLERS: Q. I understand you've drawn some conclusions here, and I'm going to ask you	16 17 18 19 20 21 22	which we marked as Exhibit 9, and the Taher paper, which has been marked as Exhibit 7; is that right? A. Yes. Q. Have you looked into what other public health authorities, other than Health Canada, have had to say about talc and
15 16 17 18 19 20 21	application of talcum powder, has significant enough correspondence with the biological experimentation literature that it allows us to draw those conclusions. BY MR. ZELLERS: Q. I understand you've drawn some	16 17 18 19 20 21	which we marked as Exhibit 9, and the Taher paper, which has been marked as Exhibit 7; is that right? A. Yes. Q. Have you looked into what other public health authorities, other than

23 (Pages 86 to 89)

	Page 90		Page 92
1	Q. Did you strike that.	1	MR. ZELLERS: I'm asking the
2	Are you familiar with the	2	doctor a question.
3	Center for Disease Control in the United	3	MS. O'DELL: Okay.
4	States?	4	MR. ZELLERS: So
5	A. Yes.	5	MS. O'DELL: That's specific
6	Q. Did you review the CDC and its	6	language, and if you have specific
7	position on any relationship between talcum	7	language that you're reading from the
8	powder and ovarian cancer?	8	report or you've taken from the
9	A. That may have been part of my	9	report, I would just ask that you show
10	review, but I don't specifically recall now	10	the doctor.
11	what the CDC has on that issue.	11	MR. ZELLERS: Ms. O'Dell, I
12	Q. CDC does not list talc or	12	have my question. I'm asking my
13	talcum powder as a risk factor for ovarian	13	question. The doctor can either
14	cancer, correct?	14	answer my question or not answer my
15	A. It's quite possible.	15	question. I'm not reading from a
16	Q. Mayo Clinic and a number of	16	document. I'm reading from my notes.
17	medical centers do not list tale as a risk	17	MS. O'DELL: I object to the
18	factor for ovarian cancer, correct?	18	form of the question. I think it's
19	A. That may be true.	19	unfair.
20	Q. Did you consider, or are you	20	MR. ZELLERS: Can you answer
21	familiar with the National Cancer Institute?	21	that question, Doctor?
22	A. I am.	22	A. I would agree that that
23	Q. National Cancer Institute is a	23	restates the general opinion of the NCI as
24	leading health authority in the United	24	published, but in order to verify the
	Page 91		Page 93
1	States; is that right?	1	specific wording, I would need to look at the
2	A. Yes.	2	document.
3	Q. Particularly in the area of	3	BY MR. ZELLERS:
4	cancer and materials that may or may not be	4	Q. Why would you rely on
5	carcinogenic; is that right?	5	Health Canada but not these other public
6	A. Well, the National Cancer	6	health organizations, including Center for
7	Institute is responsible for guiding national	7	Disease Control and the National Cancer
8	research policies as it relates to cancers,	8	Institute?
9	and that's one of their considerations is	9	A. Well, there are a number of
10	substances that may be related to cancer.	10	reasons. There are lots of public health
11	Q. When you reviewed what the	11	organizations. Many of them have different
12	National Cancer Institute has determined with	12	interests and different approaches in the way
13	respect to talcum powder and whether or not	13	that they address problems. For example,
13 14	respect to talcum powder and whether or not it is a risk factor for ovarian cancer, what	14	that they address problems. For example, discussing the National Cancer Institute, its
13 14 15	respect to talcum powder and whether or not it is a risk factor for ovarian cancer, what did you find?		that they address problems. For example, discussing the National Cancer Institute, its primary focus is on research and treatments
13 14 15 16	respect to talcum powder and whether or not it is a risk factor for ovarian cancer, what did you find? A. The most recent publication	14	that they address problems. For example, discussing the National Cancer Institute, its primary focus is on research and treatments regarding cancers, not necessarily causes,
13 14 15 16 17	respect to talcum powder and whether or not it is a risk factor for ovarian cancer, what did you find? A. The most recent publication that I viewed discounts the relationship.	14 15	that they address problems. For example, discussing the National Cancer Institute, its primary focus is on research and treatments regarding cancers, not necessarily causes, but it is a funder of basic research in the
13 14 15 16 17 18	respect to talcum powder and whether or not it is a risk factor for ovarian cancer, what did you find? A. The most recent publication that I viewed discounts the relationship. Q. In fact, the National Cancer	14 15 16 17 18	that they address problems. For example, discussing the National Cancer Institute, its primary focus is on research and treatments regarding cancers, not necessarily causes, but it is a funder of basic research in the United States.
13 14 15 16 17 18 19	respect to talcum powder and whether or not it is a risk factor for ovarian cancer, what did you find? A. The most recent publication that I viewed discounts the relationship. Q. In fact, the National Cancer Institute has concluded that the weight of	14 15 16 17 18 19	that they address problems. For example, discussing the National Cancer Institute, its primary focus is on research and treatments regarding cancers, not necessarily causes, but it is a funder of basic research in the United States. Health Canada is an
13 14 15 16 17 18 19 20	respect to talcum powder and whether or not it is a risk factor for ovarian cancer, what did you find? A. The most recent publication that I viewed discounts the relationship. Q. In fact, the National Cancer Institute has concluded that the weight of the evidence does not support an association	14 15 16 17 18	that they address problems. For example, discussing the National Cancer Institute, its primary focus is on research and treatments regarding cancers, not necessarily causes, but it is a funder of basic research in the United States. Health Canada is an organization whose charge is to is to
13 14 15 16 17 18 19 20 21	respect to talcum powder and whether or not it is a risk factor for ovarian cancer, what did you find? A. The most recent publication that I viewed discounts the relationship. Q. In fact, the National Cancer Institute has concluded that the weight of the evidence does not support an association between perineal talc exposure and increased	14 15 16 17 18 19 20 21	that they address problems. For example, discussing the National Cancer Institute, its primary focus is on research and treatments regarding cancers, not necessarily causes, but it is a funder of basic research in the United States. Health Canada is an organization whose charge is to is to synthesize public health-related positions
13 14 15 16 17 18 19 20	respect to talcum powder and whether or not it is a risk factor for ovarian cancer, what did you find? A. The most recent publication that I viewed discounts the relationship. Q. In fact, the National Cancer Institute has concluded that the weight of the evidence does not support an association between perineal talc exposure and increased risk of ovarian cancer; is that right?	14 15 16 17 18 19 20 21 22	that they address problems. For example, discussing the National Cancer Institute, its primary focus is on research and treatments regarding cancers, not necessarily causes, but it is a funder of basic research in the United States. Health Canada is an organization whose charge is to is to synthesize public health-related positions based on evidence and disseminate those to
13 14 15 16 17 18 19 20 21 22 23	respect to talcum powder and whether or not it is a risk factor for ovarian cancer, what did you find? A. The most recent publication that I viewed discounts the relationship. Q. In fact, the National Cancer Institute has concluded that the weight of the evidence does not support an association between perineal talc exposure and increased risk of ovarian cancer; is that right? MS. O'DELL: Are you reading a	14 15 16 17 18 19 20 21	that they address problems. For example, discussing the National Cancer Institute, its primary focus is on research and treatments regarding cancers, not necessarily causes, but it is a funder of basic research in the United States. Health Canada is an organization whose charge is to is to synthesize public health-related positions based on evidence and disseminate those to public the public through various
13 14 15 16 17 18 19 20 21 22	respect to talcum powder and whether or not it is a risk factor for ovarian cancer, what did you find? A. The most recent publication that I viewed discounts the relationship. Q. In fact, the National Cancer Institute has concluded that the weight of the evidence does not support an association between perineal talc exposure and increased risk of ovarian cancer; is that right?	14 15 16 17 18 19 20 21 22	that they address problems. For example, discussing the National Cancer Institute, its primary focus is on research and treatments regarding cancers, not necessarily causes, but it is a funder of basic research in the United States. Health Canada is an organization whose charge is to is to synthesize public health-related positions based on evidence and disseminate those to

24 (Pages 90 to 93)

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	Page 94		Page 96
1	for that reason, I think it's important to	1	very beginning of the public comment period,
2	look at the different focus.	2	correct?
3	Also, the Health Canada report	3	A. Yes.
4	is a more contemporaneous report, which has	4	Q. You agree that Health Canada
5	been based on more recent science than has	5	can take up to two years to either take
6	been considered either by the NCI or some of	6	action or no action at all; is that right?
7	the other public health organizations.	7	A. I don't know that to be the
8	Q. The NCI's most recent update to	8	case, but it very well could be.
9	its publication was January of 2019; is that	9	Q. How did you come to learn of
10	right?	10	the Health Canada risk assessment?
11	MS. O'DELL: Object to the	11	A. I believe the attorneys let me
12	form.	12	know about it.
13	A. It's current in terms of its	13	Q. The attorneys for plaintiffs in
14	publication. I don't know that it's January	14	this matter that retained you?
15	of '19; it may be. But it's still not based	15	A. Yes.
16	· · · · · · · · · · · · · · · · · · ·	16	
	on the most recently available literature. BY MR, ZELLERS:	1	Q. Were you involved in the Health
17		17	Canada risk assessment prior to its
18	Q. But Health Canada is; is that	18	publication?
19	right?	19	A. No.
20	A. Health Canada is based on more	20	Q. Have you submitted any comments
21	recent literature than the NCI position.	21	to Health Canada?
22	Q. Health Canada and its	22	A. Not yet.
23	assessment is based upon the meta-analysis by	23	Q. Do you intend to submit
24	Taher that we've marked as Exhibit 7; is that	24	comments to Health Canada?
	Page 95		Page 97
1	right?	1	A. I might.
2	A. It is.	2	Q. What comments do you intend to
3	MS. O'DELL: Object to the	3	submit to Health Canada?
4	form.	4	A. I haven't formulated them yet.
5	BY MR. ZELLERS:	5	Q. Outside of litigation, do you
6	Q. You have reviewed that paper	6	generally rely on draft assessments by
7	and you believe it supports and strengthens	7	regulatory agencies?
8	your opinions in this case; is that right?	8	MS. O'DELL: Object to the
9	A. Yes.	9	form.
10	Q. Does the National Cancer	10	A. Yes.
11	Institute review the peer-reviewed literature	11	BY MR. ZELLERS:
12	as it relates to risk factors for ovarian	12	Q. Are you familiar with the
13	cancer?	13	precautionary principle?
14	A. They have a number of	14	A. I am.
15	committees that are set up for that purpose,	15	Q. What is the precautionary
16	and it is it's a committee approach which	16	principle?
17	is handled by a committee chairperson. The	17	A. The precautionary principle
18	National Cancer Institute itself has some	18	states that changes should take place in the
19	oversight of that process, but they defer to	19	face of a potential hazard until that hazard
20	the committee chairs.	20	is proved not to exist. It's a general
20 21		20	
22	•	22	precept that's used in the EU, for example,
23	Canada assessment is a draft; is that right? A. Yes.	23	and very different from the one that operates
23 24		23	in this country.
4 4	Q. You understand that it's at the	4	Q. The principle in this country

25 (Pages 94 to 97)

	Page 98		Page 100
1	is that there needs to be scientific evidence	1	Did I read that correctly?
2	in order to take action; is that right?	2	A. You did.
3	MS. O'DELL: Object to the	3	Q. Is that your understanding of
4	form.	4	what a precautionary approach is?
5	A. Yes, that's correct.	5	A. Yes. In general, the
6	BY MR. ZELLERS:	6	precautionary principle can be restated that
7	Q. The precautionary principle	7	an ounce of prevention is worth a pound of
8	says even before there's full or complete	8	cure.
9	scientific demonstration of cause and effect,	9	Q. Health Canada does not require
10	it is appropriate to take a precautionary	10	a finding of causation such as required in
11	approach; is that right?	11	litigation matters in this country, the
12	A. That's right.	12	United States; is that right?
13	Q. The Health Canada follows	13	A. In order to adopt a document
14	strike that.	14	that has a significant effect on general
15	Health Canada follows and has	15	-
		1	public health practices, no, it does not.
16	adopted a precautionary approach; is that	16	Q. The Taher paper, that's another
17	right?	17	paper that you have reviewed since you
18	A. Yes.	18	published your report; is that right?
19	Q. Please review	19	A. Which paper? I'm sorry.
20	Deposition Exhibit 14.	20	Q. This is what we've marked as
21	(Carson Deposition Exhibit 14	21	Exhibit 7. You brought it with you here
22	marked.)	22	today?
23	BY MR. ZELLERS:	23	A. Okay. Yes.
24	Q. Deposition Exhibit 14 is the	24	Q. You've read the Taher 2018
	Page 99		Page 101
1	Health Canada Decision-Making Framework for	1	
_			manuscript; is that right?
2	Identifying, Assessing and Managing Health	2	manuscript; is that right? A. Yes.
3	Identifying, Assessing and Managing Health Risk.		A. Yes.
	Risk.	2	A. Yes.Q. Where did you obtain that
3		2 3 4	A. Yes. Q. Where did you obtain that manuscript from?
3 4	Risk. Do you see that? A. Yes.	2 3 4 5	A. Yes.Q. Where did you obtain that manuscript from?A. This was obtained directly from
3 4 5 6	Risk. Do you see that? A. Yes. Q. If you go to page 5 of	2 3 4 5 6	 A. Yes. Q. Where did you obtain that manuscript from? A. This was obtained directly from one of the coauthors on this study to the
3 4 5 6 7	Risk. Do you see that? A. Yes. Q. If you go to page 5 of Exhibit 14	2 3 4 5 6 7	 A. Yes. Q. Where did you obtain that manuscript from? A. This was obtained directly from one of the coauthors on this study to the plaintiffs' attorneys, who passed it along to
3 4 5 6 7 8	Risk. Do you see that? A. Yes. Q. If you go to page 5 of Exhibit 14 MS. O'DELL: Feel free to	2 3 4 5 6 7 8	 A. Yes. Q. Where did you obtain that manuscript from? A. This was obtained directly from one of the coauthors on this study to the plaintiffs' attorneys, who passed it along to me.
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3 4 5 6 7 8 9	Risk. Do you see that? A. Yes. Q. If you go to page 5 of Exhibit 14 MS. O'DELL: Feel free to take review the document if you're not familiar with it, Dr. Carson.	2 3 4 5 6 7 8 9	 A. Yes. Q. Where did you obtain that manuscript from? A. This was obtained directly from one of the coauthors on this study to the plaintiffs' attorneys, who passed it along to me. Q. So one of the coauthors on this study gave it to the plaintiffs' counsel, who
3 4 5 6 7 8 9 10	Risk. Do you see that? A. Yes. Q. If you go to page 5 of Exhibit 14 MS. O'DELL: Feel free to take review the document if you're not familiar with it, Dr. Carson. BY MR. ZELLERS:	2 3 4 5 6 7 8 9 10	A. Yes. Q. Where did you obtain that manuscript from? A. This was obtained directly from one of the coauthors on this study to the plaintiffs' attorneys, who passed it along to me. Q. So one of the coauthors on this study gave it to the plaintiffs' counsel, who then gave it to you; is that right?
3 4 5 6 7 8 9 10 11 12	Risk. Do you see that? A. Yes. Q. If you go to page 5 of Exhibit 14 MS. O'DELL: Feel free to take review the document if you're not familiar with it, Dr. Carson. BY MR. ZELLERS: Q. One of the underlying	2 3 4 5 6 7 8 9 10 11	A. Yes. Q. Where did you obtain that manuscript from? A. This was obtained directly from one of the coauthors on this study to the plaintiffs' attorneys, who passed it along to me. Q. So one of the coauthors on this study gave it to the plaintiffs' counsel, who then gave it to you; is that right? A. That's correct.
3 4 5 6 7 8 9 10 11 12 13	Risk. Do you see that? A. Yes. Q. If you go to page 5 of Exhibit 14 MS. O'DELL: Feel free to take review the document if you're not familiar with it, Dr. Carson. BY MR. ZELLERS: Q. One of the underlying principles in the Health Canada	2 3 4 5 6 7 8 9 10 11 12 13	A. Yes. Q. Where did you obtain that manuscript from? A. This was obtained directly from one of the coauthors on this study to the plaintiffs' attorneys, who passed it along to me. Q. So one of the coauthors on this study gave it to the plaintiffs' counsel, who then gave it to you; is that right? A. That's correct. Q. Who was the author of this
3 4 5 6 7 8 9 10 11 12 13 14	Risk. Do you see that? A. Yes. Q. If you go to page 5 of Exhibit 14 MS. O'DELL: Feel free to take review the document if you're not familiar with it, Dr. Carson. BY MR. ZELLERS: Q. One of the underlying principles in the Health Canada decision-making framework is use a	2 3 4 5 6 7 8 9 10 11 12 13 14	A. Yes. Q. Where did you obtain that manuscript from? A. This was obtained directly from one of the coauthors on this study to the plaintiffs' attorneys, who passed it along to me. Q. So one of the coauthors on this study gave it to the plaintiffs' counsel, who then gave it to you; is that right? A. That's correct. Q. Who was the author of this publication, Exhibit 7, that provided the
3 4 5 6 7 8 9 10 11 12 13 14 15	Risk. Do you see that? A. Yes. Q. If you go to page 5 of Exhibit 14 MS. O'DELL: Feel free to take review the document if you're not familiar with it, Dr. Carson. BY MR. ZELLERS: Q. One of the underlying principles in the Health Canada decision-making framework is use a precautionary approach; is that right?	2 3 4 5 6 7 8 9 10 11 12 13 14 15	A. Yes. Q. Where did you obtain that manuscript from? A. This was obtained directly from one of the coauthors on this study to the plaintiffs' attorneys, who passed it along to me. Q. So one of the coauthors on this study gave it to the plaintiffs' counsel, who then gave it to you; is that right? A. That's correct. Q. Who was the author of this publication, Exhibit 7, that provided the paper to plaintiffs' counsel, if you know?
3 4 5 6 7 8 9 10 11 12 13 14 15 16	Risk. Do you see that? A. Yes. Q. If you go to page 5 of Exhibit 14 MS. O'DELL: Feel free to take review the document if you're not familiar with it, Dr. Carson. BY MR. ZELLERS: Q. One of the underlying principles in the Health Canada decision-making framework is use a precautionary approach; is that right? A. That's right.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	A. Yes. Q. Where did you obtain that manuscript from? A. This was obtained directly from one of the coauthors on this study to the plaintiffs' attorneys, who passed it along to me. Q. So one of the coauthors on this study gave it to the plaintiffs' counsel, who then gave it to you; is that right? A. That's correct. Q. Who was the author of this publication, Exhibit 7, that provided the paper to plaintiffs' counsel, if you know? A. I don't recall.
3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	Risk. Do you see that? A. Yes. Q. If you go to page 5 of Exhibit 14 MS. O'DELL: Feel free to take review the document if you're not familiar with it, Dr. Carson. BY MR. ZELLERS: Q. One of the underlying principles in the Health Canada decision-making framework is use a precautionary approach; is that right? A. That's right. Q. If we go to page 8, Health	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	A. Yes. Q. Where did you obtain that manuscript from? A. This was obtained directly from one of the coauthors on this study to the plaintiffs' attorneys, who passed it along to me. Q. So one of the coauthors on this study gave it to the plaintiffs' counsel, who then gave it to you; is that right? A. That's correct. Q. Who was the author of this publication, Exhibit 7, that provided the paper to plaintiffs' counsel, if you know? A. I don't recall. Q. But one of these authors; is
3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	Risk. Do you see that? A. Yes. Q. If you go to page 5 of Exhibit 14 MS. O'DELL: Feel free to take review the document if you're not familiar with it, Dr. Carson. BY MR. ZELLERS: Q. One of the underlying principles in the Health Canada decision-making framework is use a precautionary approach; is that right? A. That's right. Q. If we go to page 8, Health Canada defines the use of a precautionary	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	A. Yes. Q. Where did you obtain that manuscript from? A. This was obtained directly from one of the coauthors on this study to the plaintiffs' attorneys, who passed it along to me. Q. So one of the coauthors on this study gave it to the plaintiffs' counsel, who then gave it to you; is that right? A. That's correct. Q. Who was the author of this publication, Exhibit 7, that provided the paper to plaintiffs' counsel, if you know? A. I don't recall. Q. But one of these authors; is that right?
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3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	Risk. Do you see that? A. Yes. Q. If you go to page 5 of Exhibit 14 MS. O'DELL: Feel free to take review the document if you're not familiar with it, Dr. Carson. BY MR. ZELLERS: Q. One of the underlying principles in the Health Canada decision-making framework is use a precautionary approach; is that right? A. That's right. Q. If we go to page 8, Health Canada defines the use of a precautionary approach, and looking at the second sentence: A precautionary approach to decision-making	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	A. Yes. Q. Where did you obtain that manuscript from? A. This was obtained directly from one of the coauthors on this study to the plaintiffs' attorneys, who passed it along to me. Q. So one of the coauthors on this study gave it to the plaintiffs' counsel, who then gave it to you; is that right? A. That's correct. Q. Who was the author of this publication, Exhibit 7, that provided the paper to plaintiffs' counsel, if you know? A. I don't recall. Q. But one of these authors; is that right? A. It would yes. Q. Why did you not include this
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3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Risk. Do you see that? A. Yes. Q. If you go to page 5 of Exhibit 14 MS. O'DELL: Feel free to take review the document if you're not familiar with it, Dr. Carson. BY MR. ZELLERS: Q. One of the underlying principles in the Health Canada decision-making framework is use a precautionary approach; is that right? A. That's right. Q. If we go to page 8, Health Canada defines the use of a precautionary approach, and looking at the second sentence: A precautionary approach to decision-making emphasizes the need to take timely and appropriate preventative action, even in the	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. Yes. Q. Where did you obtain that manuscript from? A. This was obtained directly from one of the coauthors on this study to the plaintiffs' attorneys, who passed it along to me. Q. So one of the coauthors on this study gave it to the plaintiffs' counsel, who then gave it to you; is that right? A. That's correct. Q. Who was the author of this publication, Exhibit 7, that provided the paper to plaintiffs' counsel, if you know? A. I don't recall. Q. But one of these authors; is that right? A. It would yes. Q. Why did you not include this paper on either your reliance list or your literature list?
3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Risk. Do you see that? A. Yes. Q. If you go to page 5 of Exhibit 14 MS. O'DELL: Feel free to take review the document if you're not familiar with it, Dr. Carson. BY MR. ZELLERS: Q. One of the underlying principles in the Health Canada decision-making framework is use a precautionary approach; is that right? A. That's right. Q. If we go to page 8, Health Canada defines the use of a precautionary approach, and looking at the second sentence: A precautionary approach to decision-making emphasizes the need to take timely and	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	A. Yes. Q. Where did you obtain that manuscript from? A. This was obtained directly from one of the coauthors on this study to the plaintiffs' attorneys, who passed it along to me. Q. So one of the coauthors on this study gave it to the plaintiffs' counsel, who then gave it to you; is that right? A. That's correct. Q. Who was the author of this publication, Exhibit 7, that provided the paper to plaintiffs' counsel, if you know? A. I don't recall. Q. But one of these authors; is that right? A. It would yes. Q. Why did you not include this paper on either your reliance list or your

26 (Pages 98 to 101)

	Arch I. Chip Co		
	Page 102		Page 104
1	Q. Did you have access to the	1	A. Yes, I have.
2	appendices and supplemental tables that are	2	Q. Do you know any of the authors
3	referred to in the Taher 2018 publication	3	of this paper, Exhibit 7?
4	which we've marked as Exhibit 7?	4	A. No, I don't.
5	A. The ones that are not in	5	Q. Do you know the source of
6	this in this document or	6	funding for this paper?
7	Q. Yes.	7	A. I I think the sources of
8	A. Those I have not thoroughly	8	funding are mentioned in here.
9	examined those, but I do have access to them.	9	Q. Other than what's mentioned in
10	Q. How do you have access to those	10	the paper, Exhibit 7, do you have any
11	appendices and supplemental tables?	11	knowledge as to the sources of funding?
12	A. They were also provided to me	12	A. There's a combination of
13	by plaintiffs' counsel.	13	sources. In part, this work is funded
14	Q. Has the Taher publication,	14	through the plaintiffs' attorneys.
15	which we've marked as Exhibit 7, been peer	15	Q. Have you communicated with any
16	reviewed?	16	of the authors of this paper?
17	A. It's in the process. This is a	17	A. No.
18	manuscript that's just been accepted for	18	Q. Do you know the credentials of
19	publication, so it has gone through peer	19	any of the authors of this paper?
20	review.	20	A. I haven't investigated that.
21	Q. It has gone through peer	21	Q. In your epidemiological work
22	review	22	outside of litigation, do you rely on
23	A. That's my understanding.	23	articles that are funded at least in part by
24	Q and Exhibit 7 is the article	24	plaintiffs' counsel in litigation?
21	Q and Exhibit / is the article	24	planiums counsel in hugadon:
	Page 103		Page 105
1	that you believe will be published; is that	1	A. If the articles represent good
2	right?	2	science, I don't really pay much attention or
3	A. This is a this is a working	3	worry about the funding source.
4	manuscript which has gone through at least	4	Q. Do you know what conflicts of
5	part of the peer-review process. There may	5	interest any of the authors have?
6	be minor edits that occur to this, but this	6	A. I don't know specifically. I
7	is substantially the final article.	7	can't recall if they're outlined in here.
8	Q. How do you know that?	8	But the those are also evaluated based on
9	A. That's the general process of	9	the peer-review process.
10	submitting publications to peer-reviewed	10	Q. Do you know whether some of the
11			Q. Do you know whether some of the
11	article journals.	11	authors are serving as consultants to
12	article journals. Q. How do you know I'm sorry,	11 12	•
			authors are serving as consultants to
12	Q. How do you know I'm sorry,	12	authors are serving as consultants to plaintiffs' counsel in this litigation?
12 13	Q. How do you know I'm sorry, did you finish?	12 13	authors are serving as consultants to plaintiffs' counsel in this litigation? A. I know that no, I don't know
12 13 14	Q. How do you know I'm sorry, did you finish? A. I'm finished.	12 13 14	authors are serving as consultants to plaintiffs' counsel in this litigation? A. I know that no, I don't know that. Excuse me, I gave an incorrect answer.
12 13 14 15	Q. How do you know I'm sorry, did you finish?A. I'm finished.Q. How did you know the status of	12 13 14 15	authors are serving as consultants to plaintiffs' counsel in this litigation? A. I know that no, I don't know that. Excuse me, I gave an incorrect answer. Q. Sure. Correct it, please.
12 13 14 15 16	 Q. How do you know I'm sorry, did you finish? A. I'm finished. Q. How did you know the status of the peer-review process with respect to 	12 13 14 15 16	authors are serving as consultants to plaintiffs' counsel in this litigation? A. I know that no, I don't know that. Excuse me, I gave an incorrect answer. Q. Sure. Correct it, please. A. I mentioned that part of the
12 13 14 15 16 17	Q. How do you know I'm sorry, did you finish? A. I'm finished. Q. How did you know the status of the peer-review process with respect to Exhibit 7?	12 13 14 15 16 17	authors are serving as consultants to plaintiffs' counsel in this litigation? A. I know that no, I don't know that. Excuse me, I gave an incorrect answer. Q. Sure. Correct it, please. A. I mentioned that part of the funding for this research came from
12 13 14 15 16 17	 Q. How do you know I'm sorry, did you finish? A. I'm finished. Q. How did you know the status of the peer-review process with respect to Exhibit 7? A. Because it's been accepted for 	12 13 14 15 16 17 18	authors are serving as consultants to plaintiffs' counsel in this litigation? A. I know that no, I don't know that. Excuse me, I gave an incorrect answer. Q. Sure. Correct it, please. A. I mentioned that part of the funding for this research came from plaintiffs' counsel, and I'm not I don't
12 13 14 15 16 17 18 19	 Q. How do you know I'm sorry, did you finish? A. I'm finished. Q. How did you know the status of the peer-review process with respect to Exhibit 7? A. Because it's been accepted for publication. 	12 13 14 15 16 17 18 19	authors are serving as consultants to plaintiffs' counsel in this litigation? A. I know that no, I don't know that. Excuse me, I gave an incorrect answer. Q. Sure. Correct it, please. A. I mentioned that part of the funding for this research came from plaintiffs' counsel, and I'm not I don't know that that's the case. I was thinking of
12 13 14 15 16 17 18 19 20	Q. How do you know I'm sorry, did you finish? A. I'm finished. Q. How did you know the status of the peer-review process with respect to Exhibit 7? A. Because it's been accepted for publication. Q. How do you know that?	12 13 14 15 16 17 18 19 20	authors are serving as consultants to plaintiffs' counsel in this litigation? A. I know that no, I don't know that. Excuse me, I gave an incorrect answer. Q. Sure. Correct it, please. A. I mentioned that part of the funding for this research came from plaintiffs' counsel, and I'm not I don't know that that's the case. I was thinking of another research report when I said that.
12 13 14 15 16 17 18 19 20 21	Q. How do you know I'm sorry, did you finish? A. I'm finished. Q. How did you know the status of the peer-review process with respect to Exhibit 7? A. Because it's been accepted for publication. Q. How do you know that? A. That, I was told by the	12 13 14 15 16 17 18 19 20 21	authors are serving as consultants to plaintiffs' counsel in this litigation? A. I know that no, I don't know that. Excuse me, I gave an incorrect answer. Q. Sure. Correct it, please. A. I mentioned that part of the funding for this research came from plaintiffs' counsel, and I'm not I don't know that that's the case. I was thinking of another research report when I said that. Q. Do you know whether or not, at
12 13 14 15 16 17 18 19 20 21	Q. How do you know I'm sorry, did you finish? A. I'm finished. Q. How did you know the status of the peer-review process with respect to Exhibit 7? A. Because it's been accepted for publication. Q. How do you know that? A. That, I was told by the plaintiffs' attorneys.	12 13 14 15 16 17 18 19 20 21	authors are serving as consultants to plaintiffs' counsel in this litigation? A. I know that no, I don't know that. Excuse me, I gave an incorrect answer. Q. Sure. Correct it, please. A. I mentioned that part of the funding for this research came from plaintiffs' counsel, and I'm not I don't know that that's the case. I was thinking of another research report when I said that. Q. Do you know whether or not, at least in part, funding for this paper, the

27 (Pages 102 to 105)

	Alen I. enip ea		, M.D., FII.D.
	Page 106		Page 108
1	Q. Taher, this paper, Exhibit 7,	1	factors is consistency; is that right?
2	concludes that asbestos contamination does	2	A. Yes.
3	not explain ovarian cancer, correct?	3	Q. You, in fact, are opining in
4	A. It does come to that general	4	this case that there is consistency among the
5	conclusion.	5	talcum powder ovarian cancer studies and
6	Q. That's a different conclusion	6	publications; is that right?
7	than you have formulated in this matter; is	7	A. Yes.
8	that right?	8	Q. The authors of the Taher paper
9	A. No, it's not.	9	disagree with that conclusion; is that right?
10	Q. You agree that asbestos	10	MS. O'DELL: Object to the
11	contamination does not explain ovarian	11	form.
12	cancer; is that right?	12	A. I don't think they disagree
13	A. It doesn't completely explain	13	with that.
14	ovarian cancer.	14	BY MR. ZELLERS:
15	Q. Does it explain ovarian cancer?	15	
16		16	Q. Turn to page 25, Table 2. This
	MS. O'DELL: Objection, asked	1	is, again, something that you have reviewed
17	and answered.	17 18	in preparation for your deposition; is that
18	A. I I don't believe it	1	right?
19	completely explains ovarian cancer, no.	19	A. Well, I didn't review it in
20	BY MR. ZELLERS:	20	preparation for the deposition, but I've
21	Q. Turn to page 41 of Exhibit 7.	21	reviewed it recently.
22	Look at the last three lines of the paper.	22	Q. At the request of plaintiffs'
23	The authors of the Taher publication state:	23	counsel, correct?
24	The similarity of findings between studies	24	A. Yes.
	Page 107		Page 109
1	published prior to and after this point	1	Q. Table 2 is a summary of
2	suggest asbestos contamination does not	2	evidence for each of the Hill criteria of
3	explain the positive association between	3	causation as applied to perineal application
4	perineal use of talc powder and the risk of	4	of talc and ovarian cancer.
5	ovarian cancer.	5	Do you see that?
6	Did I correctly state their	6	A. Yes.
7	conclusion?	7	Q. Under Consistency, they state
8	A. Well, there was a final clause	8	that 15 out of 30 studies reported positive
9	of the sentence, but yes, you correctly read	9	and significant associations; is that right?
10	that.	10	A. Yes.
11	Q. The Taher authors also	11	Q. 15 out of 30, that's 50%,
12	discussed the lack of consistency among the	12	right?
13	various talcum powder studies; is that right?	13	A. Yes.
14	MS. O'DELL: Object to the	14	Q. 50% is no better than a coin
15	form.	15	toss; is that right?
16	A. I'm sorry, could you repeat	16	MS. O'DELL: Object to the
17	that question?	17	form.
18	BY MR. ZELLERS:	18	A. Well, I would have to also
19	Q. Sure.	19	mention that the majority of those 30 studies
	You looked at the Bradford Hill	20	found positive associations. These are the
20	I on looked at the Diagroid Hill	21	ones that showed positive associations that
20 21	factors in formulating your opinion: is that	1 41	
21	factors in formulating your opinion; is that	1	
21 22	right?	22	rose to the level of statistical
21		1	

28 (Pages 106 to 109)

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	Page 110		Page 112
1	BY MR. ZELLERS:	1	studies that have shown a biological gradient
2	Q. If an association is not	2	at especially in relation to some of the
3	statistically significant, then it can be due	3	subtypes of ovarian cancer.
4	to chance; is that right?	4	BY MR. ZELLERS:
5	A. But if it's due to chance over	5	Q. And I'm going to ask you about
6	and over and over again, and you keep getting	6	those questions, but right now I'm just
7	a positive association, that argues very	7	asking you about the Taher paper.
8	strongly against the chance as being the only	8	A. Well, I'm trying to just
9	factor.	9	completely answer your question.
10	Q. Can you answer my question: A	10	Q. I'm asking you about the Taher
11	lack of a statistically significant	11	paper. You understand?
12	association is consistent with or can be	12	A. Yes. This is all from the
13	consistent with no risk, correct?	13	Taher paper that I read you.
14	MS. O'DELL: Objection to form,	14	Q. Section 3.3.1 talks about
15	asked and answered.	15	evidence from human studies. That's on
16	A. If you're referring to an	16	page 20; is that right?
17	individual study, that might be the case;	17	A. Yes.
18	however, when considering the Bradford Hill	18	Q. This section talks about
19	criterion of consistency, you look at the	19	whether or not there is a consistent
20	overall body of the literature and what it	20	dose-response found in those studies; is that
21	· · · · · · · · · · · · · · · · · · ·	21	
22	tells you. There's an obvious statistical	22	right? MS. O'DELL: What sentence are
		1	
23	trend toward positive connection between	23	you pointing to?
24	talcum powder perineal application and the	24	MR. ZELLERS: I'm asking the
	Page 111		Page 113
1	occurrence of ovarian cancer, and the more	1	doctor questions based upon his review
2	evidence that mounts, the more strongly that	2	of the paper, Ms. O'Dell.
3	association is proven.	3	MS. O'DELL: Okay. Feel free
4	BY MR. ZELLERS:	4	to review it, Doctor, if you need to.
5	Q. Would you say that 15 out of 30	5	THE WITNESS: I'm just taking a
6	means there are consistent results across	6	look at this section.
7	studies?	7	BY MR. ZELLERS:
8	A. I think I've just explained to	8	Q. And if it helps you, look on
9	you how I believe there are consistent	9	page 21, lines 174 through 177.
10	results across studies.	10	(Document review.)
11	Q. The authors of the Taher paper	11	BY MR. ZELLERS:
12	also conclude that they do not find a	12	Q. I only want to ask you about
13	consistent dose-response in the papers that	13	two sentences. Are you ready for me to ask
14	look at perineal application of talc and	14	you my question?
15	ovarian cancer; is that right?	15	A. Just one moment, please.
16	MS. O'DELL: Object to the	16	Q. Sure.
17	form.	17	(Document review.)
18	A. Well, what they actually say is	18	THE WITNESS: All right, I'm
19	that about half of the epidemiological	19	ready for your question.
20	studies assess only one level of talc	20	BY MR. ZELLERS:
21	exposure, ever versus never. So it's not	21	Q. The Taher paper states that
22	possible from those studies to establish a	22	many of the studies only reported on the
23	biological gradient.	23	ovarian cancer risk assessing one exposure
23 24	However, there are a number of	24	category and that exposure response analyses
2 4	However, there are a number of	4	category and that exposure response analyses
		I	

29 (Pages 110 to 113)

	Page 114		Page 116
1	were not done in all studies; is that right?	1	inflammation in the tissues in which it
2	A. Yes.	2	sequesters; is that right?
3	Q. When conducted, findings from	3	A. Yes.
4	trend analyses were not consistent; is that	4	Q. Assuming for the moment that
5	correct?	5	talc can reach the ovaries, is it your
6	MS. O'DELL: Object to the	6	opinion that tale produces chronic
7	form.	7	inflammation in the ovaries and that this
8	A. Yes.	8	somehow leads to ovarian cancer?
9	BY MR. ZELLERS:	9	A. It is my opinion that talc
10	Q. All right. With respect I'm	10	produces chronic inflammation in the
11	done with that paper.	11	epithelial tissues of the ovaries and
12	You discuss your opinion	12	surrounding epithelial tissues and leads to
13	number 1 on page 7 of your report; is that	13	both carcinogenesis initiation and promotion.
14	right?	14	Q. There are no reports in the
15	A. Yes.	15	literature of externally applied talc leading
16	Q. You first state on page 7 that	16	to inflammation, granulomas, fibrosis or
17	you believe talcum powder is immunogenic and	17	adhesions anywhere along a woman's
18	produces chronic inflammation in the tissues;	18	reproductive tract, correct?
19	is that right?	19	MS. O'DELL: Object to the
20	A. Yes.	20	form, asked and answered.
21	Q. You state that other components	21	A. Well, that's similar to the
22	in talcum powder, including mineral fibers,	22	question that you asked earlier, and although
23	asbestos, fibrous tale, carcinogenic metals	23	I'm not aware of experimental reports that
24	and other chemicals intensify the	24	specifically jive with that condition,
	Page 115		Page 117
1	inflammatory response and stimulate cell	1	certainly there are a lot of theoretical
2	growth and proliferation; is that right?	2	reports that have been published.
3	A. Yes.	3	For example, Dr. Ness' article
4	Q. Other than asbestos, what	4	from '99 lays out the theory of inflammation
5	mineral fibers in talc intensify the	5	and relates that to talc exposure from
6	inflammatory response?	6	perineal application.
7	A. Well, the endogenous fibrous	7	BY MR. ZELLERS:
8	talc fibers also intensify the response.	8	Q. This is your colleague,
9	Q. Other than asbestos and fibrous	9	Dr. Ness; is that right?
10	talc fibers, what mineral fibers in talc do	10	A. Ness, and Coussens, when she
11	you believe intensify the inflammatory	11	was at Pittsburgh.
12	response?	12	Q. Dr. Ness, you showed her your
13	A. I'm not really able to answer	13	report and asked for her comments; is that
14	that question because I don't have a specific	14	right?
	opinion about it. I'm not a geologist.	15	A. I didn't show her the report.
15		1 1 6	Q. Well, you talked to her about
16	Q. Are the other chemicals that	16	
	Q. Are the other chemicals that you refer to in this section fragrance	17	and showed her your conclusions and your
16 17 18		17 18	and showed her your conclusions and your opinions; is that right?
16 17	you refer to in this section fragrance	17	and showed her your conclusions and your
16 17 18	you refer to in this section fragrance chemicals?	17 18	and showed her your conclusions and your opinions; is that right?
16 17 18 19	you refer to in this section fragrance chemicals? A. Yes.	17 18 19	and showed her your conclusions and your opinions; is that right? A. No, I talked to her about the
16 17 18 19 20	you refer to in this section fragrance chemicals? A. Yes. Q. Any others?	17 18 19 20	and showed her your conclusions and your opinions; is that right? A. No, I talked to her about the paper.
16 17 18 19 20 21	you refer to in this section fragrance chemicals? A. Yes. Q. Any others? A. None that are intentionally	17 18 19 20 21	and showed her your conclusions and your opinions; is that right? A. No, I talked to her about the paper. Q. Her paper?

30 (Pages 114 to 117)

	Page 118		Page 120
1	in this litigation?	1	talc relating to that, and to my knowledge,
2	A. No, I didn't.	2	there are no experimental reports or case
3	Q. Did she wonder or ask why it	3	reports that can document that at the current
4	was that you were researching or looking into	4	time.
5	this issue?	5	Q. Granulomas, fibrosis and
6	A. She I think she may have,	6	adhesions do not cause ovarian cancer,
7	yeah.	7	correct?
8	Q. And what did you tell her?	8	MS. O'DELL: Object to the
9	A. I told her I had been recently	9	form.
10	asked to look into it.	10	A. The inflammatory process that
11	Q. Did you tell her that you'd	11	is intimately connected with granuloma
12	been asked to look into it by counsel for	12	formation may well be the same process that
13	plaintiffs in the talc litigation?	13	results in mutation and promotion of ovarian
14	A. No, I didn't.	14	cancer. So I I could not agree completely
15	Q. And that never came up; is that	15	with your statement.
16	right?	16	BY MR. ZELLERS:
17	A. It didn't.	17	Q. Is there a good scientific
18	Q. And she never talked to you or	18	basis today to opine that granulomas,
19	told you about her experience and her work as	19	fibrosis or adhesions cause ovarian cancer?
20	counsel strike that, as an expert for	20	MS. O'DELL: Object to the
21	plaintiffs; is that your testimony?	21	form.
22	A. Yes. It was a very brief	22	A. No, I don't think they cause
23	conversation.	23	ovarian cancer.
24	Q. If up to 50% of all U.S. women	24	///
	C		
	Page 119		Page 121
1	Page 119 have used genital talc, shouldn't there be	1	Page 121 BY MR. ZELLERS:
1 2		1 2	BY MR. ZELLERS: Q. Would you agree that not all
	have used genital talc, shouldn't there be		BY MR. ZELLERS:
2	have used genital talc, shouldn't there be studies which have shown inflammation,	2	BY MR. ZELLERS: Q. Would you agree that not all
2	have used genital talc, shouldn't there be studies which have shown inflammation, granulomas, fibrosis or adhesions in a	2 3	BY MR. ZELLERS: Q. Would you agree that not all inflammatory conditions lead to cancer?
2 3 4	have used genital talc, shouldn't there be studies which have shown inflammation, granulomas, fibrosis or adhesions in a woman's reproductive tract?	2 3 4	BY MR. ZELLERS: Q. Would you agree that not all inflammatory conditions lead to cancer? A. Yes.
2 3 4 5	have used genital talc, shouldn't there be studies which have shown inflammation, granulomas, fibrosis or adhesions in a woman's reproductive tract? MS. O'DELL: Object to the	2 3 4 5	BY MR. ZELLERS: Q. Would you agree that not all inflammatory conditions lead to cancer? A. Yes. Q. It's true that all of us
2 3 4 5 6	have used genital talc, shouldn't there be studies which have shown inflammation, granulomas, fibrosis or adhesions in a woman's reproductive tract? MS. O'DELL: Object to the form.	2 3 4 5 6	BY MR. ZELLERS: Q. Would you agree that not all inflammatory conditions lead to cancer? A. Yes. Q. It's true that all of us experience inflammatory reactions of one sort
2 3 4 5 6 7	have used genital talc, shouldn't there be studies which have shown inflammation, granulomas, fibrosis or adhesions in a woman's reproductive tract? MS. O'DELL: Object to the form. A. Well, there are studies that	2 3 4 5 6 7	BY MR. ZELLERS: Q. Would you agree that not all inflammatory conditions lead to cancer? A. Yes. Q. It's true that all of us experience inflammatory reactions of one sort or another, including chronic conditions,
2 3 4 5 6 7 8	have used genital talc, shouldn't there be studies which have shown inflammation, granulomas, fibrosis or adhesions in a woman's reproductive tract? MS. O'DELL: Object to the form. A. Well, there are studies that show those things.	2 3 4 5 6 7 8	BY MR. ZELLERS: Q. Would you agree that not all inflammatory conditions lead to cancer? A. Yes. Q. It's true that all of us experience inflammatory reactions of one sort or another, including chronic conditions, that do not lead to cancer, correct?
2 3 4 5 6 7 8 9	have used genital talc, shouldn't there be studies which have shown inflammation, granulomas, fibrosis or adhesions in a woman's reproductive tract? MS. O'DELL: Object to the form. A. Well, there are studies that show those things. BY MR. ZELLERS:	2 3 4 5 6 7 8	BY MR. ZELLERS: Q. Would you agree that not all inflammatory conditions lead to cancer? A. Yes. Q. It's true that all of us experience inflammatory reactions of one sort or another, including chronic conditions, that do not lead to cancer, correct? A. That's correct. Although there
2 3 4 5 6 7 8 9	have used genital talc, shouldn't there be studies which have shown inflammation, granulomas, fibrosis or adhesions in a woman's reproductive tract? MS. O'DELL: Object to the form. A. Well, there are studies that show those things. BY MR. ZELLERS: Q. Please, tell me the published	2 3 4 5 6 7 8 9	BY MR. ZELLERS: Q. Would you agree that not all inflammatory conditions lead to cancer? A. Yes. Q. It's true that all of us experience inflammatory reactions of one sort or another, including chronic conditions, that do not lead to cancer, correct? A. That's correct. Although there is a strong relationship between inflammatory
2 3 4 5 6 7 8 9 10	have used genital talc, shouldn't there be studies which have shown inflammation, granulomas, fibrosis or adhesions in a woman's reproductive tract? MS. O'DELL: Object to the form. A. Well, there are studies that show those things. BY MR. ZELLERS: Q. Please, tell me the published studies that demonstrate inflammation,	2 3 4 5 6 7 8 9 10	BY MR. ZELLERS: Q. Would you agree that not all inflammatory conditions lead to cancer? A. Yes. Q. It's true that all of us experience inflammatory reactions of one sort or another, including chronic conditions, that do not lead to cancer, correct? A. That's correct. Although there is a strong relationship between inflammatory processes and the occurrence of cancers, and
2 3 4 5 6 7 8 9 10 11	have used genital talc, shouldn't there be studies which have shown inflammation, granulomas, fibrosis or adhesions in a woman's reproductive tract? MS. O'DELL: Object to the form. A. Well, there are studies that show those things. BY MR. ZELLERS: Q. Please, tell me the published studies that demonstrate inflammation, granulomas, fibrosis or adhesions in a	2 3 4 5 6 7 8 9 10 11	BY MR. ZELLERS: Q. Would you agree that not all inflammatory conditions lead to cancer? A. Yes. Q. It's true that all of us experience inflammatory reactions of one sort or another, including chronic conditions, that do not lead to cancer, correct? A. That's correct. Although there is a strong relationship between inflammatory processes and the occurrence of cancers, and some of those inflammatory diseases that
2 3 4 5 6 7 8 9 10 11 12 13	have used genital talc, shouldn't there be studies which have shown inflammation, granulomas, fibrosis or adhesions in a woman's reproductive tract? MS. O'DELL: Object to the form. A. Well, there are studies that show those things. BY MR. ZELLERS: Q. Please, tell me the published studies that demonstrate inflammation, granulomas, fibrosis or adhesions in a woman's reproductive tract from externally applied talc?	2 3 4 5 6 7 8 9 10 11 12 13	BY MR. ZELLERS: Q. Would you agree that not all inflammatory conditions lead to cancer? A. Yes. Q. It's true that all of us experience inflammatory reactions of one sort or another, including chronic conditions, that do not lead to cancer, correct? A. That's correct. Although there is a strong relationship between inflammatory processes and the occurrence of cancers, and some of those inflammatory diseases that you're referring to also have associations
2 3 4 5 6 7 8 9 10 11 12 13 14	have used genital talc, shouldn't there be studies which have shown inflammation, granulomas, fibrosis or adhesions in a woman's reproductive tract? MS. O'DELL: Object to the form. A. Well, there are studies that show those things. BY MR. ZELLERS: Q. Please, tell me the published studies that demonstrate inflammation, granulomas, fibrosis or adhesions in a woman's reproductive tract from externally applied talc?	2 3 4 5 6 7 8 9 10 11 12 13 14	BY MR. ZELLERS: Q. Would you agree that not all inflammatory conditions lead to cancer? A. Yes. Q. It's true that all of us experience inflammatory reactions of one sort or another, including chronic conditions, that do not lead to cancer, correct? A. That's correct. Although there is a strong relationship between inflammatory processes and the occurrence of cancers, and some of those inflammatory diseases that you're referring to also have associations with increased rates of cancers.
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	have used genital talc, shouldn't there be studies which have shown inflammation, granulomas, fibrosis or adhesions in a woman's reproductive tract? MS. O'DELL: Object to the form. A. Well, there are studies that show those things. BY MR. ZELLERS: Q. Please, tell me the published studies that demonstrate inflammation, granulomas, fibrosis or adhesions in a woman's reproductive tract from externally applied talc? A. Well, you're adding a new condition now. Q. I'm sorry if I didn't add that before. A. There are multiple studies that show inflammation and other inflammatory reactions in connection with the occurrence	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	BY MR. ZELLERS: Q. Would you agree that not all inflammatory conditions lead to cancer? A. Yes. Q. It's true that all of us experience inflammatory reactions of one sort or another, including chronic conditions, that do not lead to cancer, correct? A. That's correct. Although there is a strong relationship between inflammatory processes and the occurrence of cancers, and some of those inflammatory diseases that you're referring to also have associations with increased rates of cancers. MR. ZELLERS: Move to strike as nonresponsive. BY MR. ZELLERS: Q. Rheumatoid arthritis is an inflammatory condition; is that right? A. Yes, it is. Q. Does it increase the risk of

31 (Pages 118 to 121)

	Page 122		Page 124
1	think it may be associated with other	1	A. This is a list that I've put
2	cancers.	2	together of some of the studies I've
3	Q. Does strike that.	3	considered and how they relate to things I
4	Is psoriasis an inflammatory	4	might testify to today.
5	condition?	5	Q. Why did you not tell me about
6	A. Generally, it is.	6	your list that you brought with you today
7	Q. Is it associated with an	7	before now?
8	increased risk of ovarian cancer?	8	A. Well, I'm telling you about it
9	A. Not that I'm aware.	9	now.
10	Q. In your report you state that	10	Q. My question is why did you not,
11	inflammation is a normal body process that	11	when I asked you what you brought to the
12	leads to the thwarting of infection and rapid	12	deposition today, not take the list out and
13	healing; is that right?	13	show us the list?
14	A. That's correct.	14	A. I didn't think of it.
15	Q. If your inflammation theory is	15	Q. Okay. We'll mark your list as
16	correct, why doesn't inflammation generally,	16	Deposition Exhibit 15.
17	such as in pelvic inflammatory disease, cause	17	(Carson Deposition Exhibit 15
18	ovarian cancer?	18	marked.)
19	A. It may do so.	19	BY MR. ZELLERS:
20	Q. You are opining under oath here	20	Q. These are a number of notes,
21	that pelvic inflammatory disease causes	21	four pages of notes. Are these all your
22	ovarian cancer?	22	notes?
23	A. I think there are experts who	23	A. Yes.
24	have concluded that.	24	Q. First page has got a section of
	Page 123		Page 125
1	Q. What study are you relying on	1	articles on asbestos and ovarian cancer; is
2	for that opinion or statement?	2	that right?
3	A. That's not part of the opinions	3	A. Yes.
4	that I've been asked to consider in this	4	Q. It also has inflammation and
5	in this case.	5	cancer and a number of studies; is that
6	Q. As you sit here, can you cite	6	right?
7	me a publication or a study that finds that	7	A. Yes.
8	pelvic inflammatory disease causes ovarian	8	Q. Second page has got cohort,
9	cancer?	9	where you've listed out the four cohort
10	MS. O'DELL: Object to the	10	studies; is that right?
11	form.	11	A. Yes.
12	A. Well, I have I have a list	12	Q. Beneath that are the
13	of studies that relate inflammation to	13	meta-analyses where you've listed those out
14	ovarian cancer and other cancers.	14	and made some notes on those, correct?
15	BY MR. ZELLERS:	15	A. Yes.
16	Q. Can you name me a study or a	16	Q. The back page of the second
17	publication?	17	page has got a listing of a number of the
18	A. Okay. I think I have my list	18	case-control studies, correct?
19	here.	19	A. Yes. Those are duplicated on
20	Q. You brought other materials	20	another page.
21	with you?	21	Q. The third page has got a
		1	
22	A. I brought this list.	22	section on migration and studies that you're
22 23	A. I brought this list.Q. All right. Well, what list are	23	looking at for that proposition, correct?
22	A. I brought this list.		

32 (Pages 122 to 125)

	Arch 1. "Chip" Ca		
	Page 126		Page 128
1	Q. Underneath that, ovarian cancer	1	authors conclude that pelvic inflammatory
2	risk; is that right?	2	disease causes ovarian cancer? Do you
3	A. Yes.	3	believe each of the authors in the studies
4	Q. Underneath that, talc and other	4	that you've identified, that their studies
5	cancer; is that right?	5	stand for that proposition?
6	A. Yes.	6	MS. O'DELL: Object to form,
7	Q. And then on the last page,	7	asked and answered.
8	page 4, is a listing of the case-control	8	A. I think all of the studies that
9	studies with the odds ratios and confidence	9	I've identified for this question do allude
10	intervals; is that right?	10	to that, yes.
11	A. For the most part, yes.	11	BY MR. ZELLERS:
12	Q. All right. So looking now at	12	Q. That pelvic inflammatory
13	your list of studies that you have prepared,	13	disease causes ovarian cancer, correct?
14	which study demonstrates or supports the	14	A. That it is a it's a factor,
15	proposition that pelvic inflammatory disease	15	
16	causes ovarian cancer?	16	yes. O It's a cause. That's what they
17		17	Q. It's a cause. That's what they
18	A. Looking through here, I don't	18	state in those papers, right?
	have that item specifically in my notes, but	l	MS. O'DELL: Object to the
19	I'm just using my notes to refresh my memory	19	form.
20	about the individual research report. I	20	BY MR. ZELLERS:
21	think the Coussens and Werb paper from 2010	21	Q. That's your testimony?
22	talks about general mechanisms of	22	MS. O'DELL: Excuse me,
23	inflammation in relation to the occurrence of	23	misstates his testimony. Object to
24	ovarian cancer.	24	the form.
	Page 127		Page 129
1	And there's the Ness and	1	A. I would say it's a factor and
2	Cottreau paper from '99.	2	leave it at that.
3	Okada has discussed it in the	3	BY MR. ZELLERS:
4	2007 paper. And there's a paper from 2001	4	Q. All right. Are you familiar
5	which is Balkwill and Mantovani which	5	with pleurodesis?
6	discusses the relationship between talc and	6	A. I am.
7	ovarian cancer and also discusses the	7	Q. Does a pleurodesis cause
8	relationship to other sources of	8	cancer?
9	inflammation.	9	A. It is not known to, although it
10	Q. Each of those papers that	10	might.
11	you've identified you believe state that	11	Q. Are you familiar with the
12	pelvic inflammatory disease is a cause of	12	study, 1979, A survey of the long-term
13	ovarian cancer, correct?	13	effects of talc and kaolin pleurodesis?
14	MS. O'DELL: Object to the	14	A. Can tell me who the author of
15	form.	15	that was?
16	A. Well, I don't think they state	16	
17			
18	that in so many words, but if you read the	17	from the Research Committee of the British
	paper and you understand that what pelvic	18	Thoracic Association. The members of the
19 20	inflammatory disease is and its relationship	19	subcommittee were Chappell, Johnson, Charles,
	to inflammatory processes in general, yes,	20	Wagner, Seal, Berry and Nicholson.
	Thora tribat that'ea corner	21	Are you familiar with that
21	that's what they're saying.		
21 22	BY MR. ZELLERS:	22	paper?
21		22 23 24	

33 (Pages 126 to 129)

	Dama 120		Dama 120
	Page 130		Page 132
1	Q. We'll take a look at it. We'll	1	form.
2	mark it as Deposition Exhibit 16.	2	A. I think that was the hypothesis
3	(Carson Deposition Exhibit 16	3	of those research reports.
4	marked.)	4	BY MR. ZELLERS:
5	A. Thank you.	5	Q. And, in fact, the NSAID studies
6	MS. O'DELL: Thank you.	6	do not find a consistent causal reduction in
7	BY MR. ZELLERS:	7	the risk of ovarian cancer; is that right?
8	Q. This was a study that looked at	8	A. I think that's correct.
9	the association between pleurodesis and lung	9	Q. In your report you also state
10	cancer; is that right?	10	that studies show that use of cornstarch
11	A. Yes.	11	instead of talcum powder reduces the risk of
12	Q. It's a study that you cite on	12	ovarian cancer; is that right?
13	page 1 of your literature list; is that	13	A. Yes.
14	right?	14	Q. If inflammation causes cancer,
15	A. Okay. Yes.	15	why would cornstarch be a superior
16	Q. So you've read it; is that	16	alternative to talc?
17	right?	17	A. The reason is that cornstarch,
18	A. I have.	18	being a biological product, is much it
19	Q. You've considered it; is that	19	does have a rapid clearance from the body,
20	right?	20	even when sequestered, in comparison with a
21	A. Yes.	21	mineral substance like talc.
22	Q. They looked at 210 patients	22	Q. Well, in fact, cornstarch
23	that underwent a pleurodesis with talc or	23	causes or increases the risk of inflammation,
24	kaolin 14 to 40 years before; is that right?	24	granulomas, fibrosis and adhesions, correct?
	internal 1. to 10 years 001010, is that right.		grandional, notono and admostono, correcti
	Page 131		Page 133
1	A. That's correct.	1	A. It may, yes.
2	Q. And they found that there was	2	Q. Just like you claim talcum
3	no increased incidence of lung cancer and no	3	powder increases the risk of inflammation,
4	cases of mesothelioma; is that right?	4	granulomas, fibrosis and adhesions; is that
5	A. That's correct.	5	right?
6	Q. Why don't well, strike that.	6	MS. O'DELL: Object to the
7	You're aware of the studies	7	form.
8	that have looked at antiinflammatory drugs	8	A. I think you are you're
9	and aspirin use with respect to whether or	9	parsing terms here. That list of things were
10	not they're associated with let me	10	your words. I was agreeing with the
11	withdraw that.	11	relationship between talc and inflammation in
12	Are you familiar with the NSAID	12	ovarian epithelial tissue and the production
13	and aspirin use studies relating to the	13	or granulomas. I did not discuss the
		14	relationship between talc and adhesions or
14	incidence of ovarian cancer in chronic users?		
	A. I'm familiar with some of	15	fibrosis. There was one other thing on your
14		15 16	fibrosis. There was one other thing on your list.
14 15	A. I'm familiar with some of those, yes.		· · · · · · · · · · · · · · · · · · ·
14 15 16	A. I'm familiar with some of those, yes.Q. If your theory is correct that	16	list.
14 15 16 17	A. I'm familiar with some of those, yes. Q. If your theory is correct that inflammation causes ovarian cancer, then you	16 17	list. BY MR. ZELLERS: Q. Well, in fact, the FDA has
14 15 16 17 18	A. I'm familiar with some of those, yes. Q. If your theory is correct that inflammation causes ovarian cancer, then you would expect that the studies of NSAIDs and	16 17 18 19	list. BY MR. ZELLERS: Q. Well, in fact, the FDA has banned the use of cornstarch as a powder for
14 15 16 17 18 19 20	A. I'm familiar with some of those, yes. Q. If your theory is correct that inflammation causes ovarian cancer, then you would expect that the studies of NSAIDs and aspirin use, antiinflammatory drugs that	16 17 18	list. BY MR. ZELLERS: Q. Well, in fact, the FDA has banned the use of cornstarch as a powder for lubricating surgical gloves; is that right?
14 15 16 17 18 19 20 21	A. I'm familiar with some of those, yes. Q. If your theory is correct that inflammation causes ovarian cancer, then you would expect that the studies of NSAIDs and aspirin use, antiinflammatory drugs that reduce inflammation, would consistently	16 17 18 19 20 21	list. BY MR. ZELLERS: Q. Well, in fact, the FDA has banned the use of cornstarch as a powder for lubricating surgical gloves; is that right? A. It has, but that's not the
14 15 16 17 18 19 20 21	A. I'm familiar with some of those, yes. Q. If your theory is correct that inflammation causes ovarian cancer, then you would expect that the studies of NSAIDs and aspirin use, antiinflammatory drugs that	16 17 18 19 20 21 22	list. BY MR. ZELLERS: Q. Well, in fact, the FDA has banned the use of cornstarch as a powder for lubricating surgical gloves; is that right? A. It has, but that's not the reason.
14 15 16 17 18 19 20 21	A. I'm familiar with some of those, yes. Q. If your theory is correct that inflammation causes ovarian cancer, then you would expect that the studies of NSAIDs and aspirin use, antiinflammatory drugs that reduce inflammation, would consistently reduce the incidence of ovarian cancer,	16 17 18 19 20 21	list. BY MR. ZELLERS: Q. Well, in fact, the FDA has banned the use of cornstarch as a powder for lubricating surgical gloves; is that right? A. It has, but that's not the

34 (Pages 130 to 133)

	Page 134		Page 136
1	presented an unreasonable and substantial	1	Q. Why do you have to have a
2	risk of illness or injury and that that risk	2	special definition of "oxidative stress"?
3	cannot be corrected or eliminated by	3	I'm asking simply: Is there a publication or
4	labeling, correct?	4	a study which documents that oxidative stress
5	A. I don't know the specific	5	is involved in the development of ovarian
6	language. It looks like you're reading from	6	cancer?
7	a Federal Register document.	7	MS. O'DELL: Object to the
8	The main reason that cornstarch	8	form.
9	has been banned as a lubricant in gloves is	9	A. Sure.
10	because of the potential for transmission of	10	BY MR. ZELLERS:
11	primarily respiratory problems through	11	Q. And what paper are you going to
12		12	point me to?
	inhalation, mostly by co-workers, not by	13	•
13	patients.		A. Well, I'll point you to the
14	Q. You do agree that cornstarch	14	Ness paper to begin with, because it was one
15	has been banned by the FDA for use in	15	of the earlier papers that related oxidative
16	surgical gloves; is that right?	16	stress from talc to the occurrence of ovarian
17	A. All powdered gloves have been	17	cancer. But the relationship between
18	essentially banned from hospitals and	18	inflammation, which essentially is the source
19	operating rooms now.	19	of the oxidative stress, and cancer goes all
20	Q. You also talk about	20	the way back into the 19th Century in terms
21	inflammation and oxidative stress; is that	21	of its proposal as a rationale.
22	right?	22	Q. Is oxidative stress a variation
23	A. Yes.	23	of inflammation as you're using that term
24	Q. Does the presence of oxidative	24	relating to a potential cause of ovarian
	Page 135		Page 137
1	stress in a tissue indicate that cancer will	1	cancer?
2	develop in that tissue?	2	A. It's a component of
3	A. No.	3	-
4			inflammation.
	O. If exposure to a substance		inflammation. O. As a toxicologist, how would
5	Q. If exposure to a substance causes oxidative stress in certain tissue.	4	Q. As a toxicologist, how would
5 6	causes oxidative stress in certain tissue,	4 5	Q. As a toxicologist, how would you define fibrous talc?
6	causes oxidative stress in certain tissue, does that mean exposure of all other tissues	4 5 6	Q. As a toxicologist, how would you define fibrous talc? A. Fibrous talc is a form of talc
6 7	causes oxidative stress in certain tissue, does that mean exposure of all other tissues to that substance will cause oxidative stress	4 5 6 7	Q. As a toxicologist, how would you define fibrous tale?A. Fibrous tale is a form of tale that is conformed into elongated structures
6 7 8	causes oxidative stress in certain tissue, does that mean exposure of all other tissues to that substance will cause oxidative stress in those tissues?	4 5 6 7 8	Q. As a toxicologist, how would you define fibrous tale? A. Fibrous tale is a form of tale that is conformed into elongated structures that have an aspect ratio of length greater
6 7 8 9	causes oxidative stress in certain tissue, does that mean exposure of all other tissues to that substance will cause oxidative stress in those tissues? A. Not necessarily.	4 5 6 7 8 9	Q. As a toxicologist, how would you define fibrous talc? A. Fibrous talc is a form of talc that is conformed into elongated structures that have an aspect ratio of length greater than width that is different from the
6 7 8 9 10	causes oxidative stress in certain tissue, does that mean exposure of all other tissues to that substance will cause oxidative stress in those tissues? A. Not necessarily. Q. Does the body have protective	4 5 6 7 8 9	Q. As a toxicologist, how would you define fibrous talc? A. Fibrous talc is a form of talc that is conformed into elongated structures that have an aspect ratio of length greater than width that is different from the majority of talc which is the platy form.
6 7 8 9 10 11	causes oxidative stress in certain tissue, does that mean exposure of all other tissues to that substance will cause oxidative stress in those tissues? A. Not necessarily. Q. Does the body have protective mechanisms that can limit tissue damage from	4 5 6 7 8 9 10	Q. As a toxicologist, how would you define fibrous talc? A. Fibrous talc is a form of talc that is conformed into elongated structures that have an aspect ratio of length greater than width that is different from the majority of talc which is the platy form. Q. Do you consider yourself to be
6 7 8 9 10 11	causes oxidative stress in certain tissue, does that mean exposure of all other tissues to that substance will cause oxidative stress in those tissues? A. Not necessarily. Q. Does the body have protective mechanisms that can limit tissue damage from oxidative stress?	4 5 6 7 8 9 10 11	Q. As a toxicologist, how would you define fibrous talc? A. Fibrous talc is a form of talc that is conformed into elongated structures that have an aspect ratio of length greater than width that is different from the majority of talc which is the platy form. Q. Do you consider yourself to be an expert on fibrous talc?
6 7 8 9 10 11 12	causes oxidative stress in certain tissue, does that mean exposure of all other tissues to that substance will cause oxidative stress in those tissues? A. Not necessarily. Q. Does the body have protective mechanisms that can limit tissue damage from oxidative stress? A. Yes.	4 5 6 7 8 9 10 11 12 13	Q. As a toxicologist, how would you define fibrous talc? A. Fibrous talc is a form of talc that is conformed into elongated structures that have an aspect ratio of length greater than width that is different from the majority of talc which is the platy form. Q. Do you consider yourself to be an expert on fibrous talc? A. No, I don't.
6 7 8 9 10 11 12 13	causes oxidative stress in certain tissue, does that mean exposure of all other tissues to that substance will cause oxidative stress in those tissues? A. Not necessarily. Q. Does the body have protective mechanisms that can limit tissue damage from oxidative stress? A. Yes. Q. Do all substances that cause	4 5 6 7 8 9 10 11 12 13 14	Q. As a toxicologist, how would you define fibrous tale? A. Fibrous tale is a form of tale that is conformed into elongated structures that have an aspect ratio of length greater than width that is different from the majority of tale which is the platy form. Q. Do you consider yourself to be an expert on fibrous tale? A. No, I don't. Q. Do you consider yourself to be
6 7 8 9 10 11 12 13 14 15	causes oxidative stress in certain tissue, does that mean exposure of all other tissues to that substance will cause oxidative stress in those tissues? A. Not necessarily. Q. Does the body have protective mechanisms that can limit tissue damage from oxidative stress? A. Yes. Q. Do all substances that cause oxidative stress also cause cancer?	4 5 6 7 8 9 10 11 12 13 14 15	Q. As a toxicologist, how would you define fibrous tale? A. Fibrous tale is a form of tale that is conformed into elongated structures that have an aspect ratio of length greater than width that is different from the majority of tale which is the platy form. Q. Do you consider yourself to be an expert on fibrous tale? A. No, I don't. Q. Do you consider yourself to be an expert on oxidative stress?
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6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	causes oxidative stress in certain tissue, does that mean exposure of all other tissues to that substance will cause oxidative stress in those tissues? A. Not necessarily. Q. Does the body have protective mechanisms that can limit tissue damage from oxidative stress? A. Yes. Q. Do all substances that cause oxidative stress also cause cancer? A. I'm not sure the answer to that question is known. Q. Are there any studies or publications that indicate that oxidative stress is involved in the development of ovarian cancer?	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Q. As a toxicologist, how would you define fibrous tale? A. Fibrous tale is a form of tale that is conformed into elongated structures that have an aspect ratio of length greater than width that is different from the majority of tale which is the platy form. Q. Do you consider yourself to be an expert on fibrous tale? A. No, I don't. Q. Do you consider yourself to be an expert on oxidative stress? A. I have dealt a lot with issues of oxidative stress and health effects resulting from it. Q. Do you consider yourself to be an expert in oxidative stress? MS. O'DELL: Objection, asked

35 (Pages 134 to 137)

	Page 138		Page 140
1	regarding my professional understanding and	1	reports, the epidemiology first, is looking
2	training.	2	at the relationship between perineal use of
3	BY MR. ZELLERS:	3	dusting powders, talcum powders and ovarian
4	Q. You've never been involved in	4	cancer.
5	terms of any research or publication on the	5	Although there have been
6	subject of oxidative stress and any	6	efforts in some of those studies to
7	association with ovarian cancer, correct?	7	characterize the proportion or the
8	A. Not in terms of ovarian cancer,	8	ingredients that would be either asbestos or
9	no.	9	fibers, that's not done in all cases, and
10	Q. You have not been involved in	10	it's not ruled out in any cases.
11	any research or publication relating to the	11	The also, the research
12	subject of inflammation and its association	12	studies that have been performed, the
13	with ovarian cancer, correct?	13	testing, for example, of the products
14	A. No. All right. Yes, correct.	14	themselves are replete with reports of
15	Q. Yes, it is correct? Okay.	15	components of these powders that are fibrous
16	You claim that the presence of	16	in nature.
17	asbestos and fibrous talc further intensifies	17	MR. ZELLERS: Move to strike as
18	the carcinogenic effect of tale; is that	18	nonresponsive.
19	right?	19	BY MR. ZELLERS:
20	A. Yes.	20	Q. Do you believe that all talcum
21	Q. Is that statement different	21	powder products that are on the market
22	from the statement directly above where you	22	contain asbestos?
23	allege that asbestos and mineral fibers	23	MS. O'DELL: Object to the
24	intensify the inflammatory response and	24	form.
	Page 139		Page 141
1	stimulate the cell growth and proliferation?	1	A. I don't know.
2	A. It's not different, no.	2	BY MR. ZELLERS:
3	Q. Are your opinions dependent on	3	Q. Does it matter to your opinion
4	tale containing carcinogenic asbestos and/or	4	as to whether or not the talcum powder
5	fibrous talc?	5	products, and particularly the talcum powder
6	A. No.	6	products involved in this case, contain
7	Q. Do you believe that talcum	7	asbestos?
8	powder without asbestos causes ovarian	8	A. I wouldn't have a way to be
9	cancer?	9	able to answer that yes or no.
10	A. I believe talcum powder causes	10	Q. Do you strike that.
11	ovarian cancer. I have not seen any research	11	Have you reached a conclusion
12	done on talcum powder that has been shown not	12	as to whether or not the talcum powder
13	to contain asbestos.	13	products involved in this case contain
14	Q. Your assumption that you have	14	fibrous tale?
15	made in formulating your opinions here is	15	A. I think that most of them do.
16	that talcum powder contains asbestos; is that	16	Q. Does all of the talcum powder
17	right?	17	contain fibrous talc or just some of it?
18	A. No.	18	A. Certainly a lot of it does.
19	Q. What assumption have you made	19	Q. The basis for your conclusion
20	as to whether or not talcum powder contains	20	that the talcum powder at issue in this case
21	either asbestos or fibrous talc?	21	contains fibrous talc is the testing reports
22	MS. O'DELL: Object to the	22	that plaintiffs' attorneys gave you?
	•	1 00	
23	form.	23	MS. O'DELL: Object to the
	form. A. Looking at the research	23	form.

36 (Pages 138 to 141)

	Page 142	Γ	Dago 144
	Page 142		Page 144
1	A. Yes. Also Longo's publications	1	MS. O'DELL: Object to the
2	and reports.	2	form.
3	BY MR. ZELLERS:	3	A. That wasn't my charge. I defer
4	Q. You have reviewed the Longo	4	to the other experts in this case.
5	reports; is that right?	5	BY MR. ZELLERS:
6	A. Yes.	6	Q. Do you have an opinion on what
7	Q. Have you ever met with him?	7	type of asbestos you believe is in the talcum
8	A. No.	8	powder products at issue in this case?
9	Q. Do you know his qualifications?	9	A. Well, there have been various
10	 A. I looked at his qualifications 	10	types shown, but I think for the most part
11	at one point, but I don't recall exactly what	11	it's tremolite and anthophyllite.
12	it is at this stage.	12	Q. Are you familiar with
13	Q. Ever hear of him before this	13	crocidolite?
14	lawsuit, your getting involved in the talc	14	A. Yes.
15	litigation back in October of 2018?	15	Q. Is crocidolite found in talcum
16	A. No.	16	powder or baby powder?
17	Q. Have you reviewed any of	17	A. It's not commonly found in it.
18	Longo's testing where he did not find	18	Q. You believe that the
19	asbestos?	19	asbestos types of asbestos that may be in
20	A. I the only thing I've	20	the talcum powder at issue in this case is
21	reviewed are what's present in those reports	21	tremolite and acidolite [sic]?
22	that I cited.	22	MS. O'DELL: Objection.
23		23	A. Anthophyllite. There are
24	Q. Were you provided by counsel for plaintiffs with any testing reports from	24	others found, but you asked for most common.
21	for plantins with any testing reports from		others round, but you asked for most common.
	Page 143		Page 145
1	Longo where he did not find asbestos?	1	BY MR. ZELLERS:
2	A. There are some of those listed	2	Q. Most common you believe are
3	in his reports.	3	tremolite and anthophyllite?
4	Q. Have you reviewed the FDA's	4	A. Anthophyllite.
5	testing of talcum powder products?	5	Q. Anthophyllite. Those two; is
6	A. The FDA didn't really do much	6	that right?
7	testing of talcum powder products.	7	A. Yes.
8	Q. Have you reviewed the FDA's	8	Q. What types of asbestos are
9	testing of talcum powder products?	9	associated with ovarian cancer?
10	MS. O'DELL: Objection, vague.	10	A. Well, I'll go back to my list
11	A. The only FDA testing that I	11	again. Crocidolite is associated with
12	looked at was the I have it referenced in	12	ovarian cancer in the Acheson report from
13	my list, but the FDA, based on a	13	1982, which was from female gas mask
14	recommendation, requested samples from	14	manufacturers in England who made gas masks
15	various companies, I think nine different	15	during the period of the Second World War,
16	sources of tale. They received four and	16	and crocidolite is associated with that with
	tested those. And based on their test method	1	
17 18		17	a fairly high relative risk of 2.96.
	determined that there was not a not	18	Chrysotile asbestos had also a positive
	evidence of a significant hazard.	19	relative risk of 1.74.
19)()	There was a study of factory
19 20	BY MR. ZELLERS:	20	
19 20 21	BY MR. ZELLERS: Q. Have you made any effort to	21	workers and pipe laggers in east London,
19 20 21 22	BY MR. ZELLERS: Q. Have you made any effort to quantify the amount of any alleged	21 22	workers and pipe laggers in east London, which is the Berry report from 2000, that
19 20 21	BY MR. ZELLERS: Q. Have you made any effort to	21	workers and pipe laggers in east London,

37 (Pages 142 to 145)

	Page 146		Page 148
1	cement products and plasters, so the	1	But based on my current
2	Q. What type of asbestos, if you	2	understanding, I don't believe they've ever
3	know?	3	been totally successful in doing so.
4	A. That would have been primarily	4	So in answer to your question,
5	amphibole asbestos types, which would include	5	which I think was, was there ever a point in
6	crocidolite and tremolite and anthophyllite,	6	time where you believe the talcum powder
7	amosite is in that category.	7	products involved in this case were not
8	Bertolotti in 2008 published a	8	contaminated with asbestos, no.
9	report actually, there were several	9	BY MR. ZELLERS:
10	reports that resulted from the Eternit	10	Q. You cite in your report,
11	factory studies in Casale Monferrato in	11	page 5, to two exhibits to the depositions of
12	Italy, which was a plant that manufactured	12	John Hopkins and Julie Pier in support of
13	cement sheet and corrugated tubing, and there	13	your opinion that talcum powder products
14	were a number of studies that showed elevated	14	contain asbestos; is that right?
15	relative risks in persons exposed to asbestos	15	A. That's correct.
16	in that work, and that would also have been	16	Q. Looking at page 5, footnote 1,
17	amphibole asbestos types.	17	you cite to Exhibit Hopkins-28 in the Hopkins
18		18	• •
	Q. The studies that you've recited		deposition and Exhibit Pier-47 in the Pier
19	for us, those are all occupational studies;	19	deposition; is that right?
20	is that right?	20	A. That's correct.
21	A. Yes. I've got a lot more.	21	Q. Are you aware that those
22	Q. Well, and it's on your list,	22	exhibits were created by plaintiffs' counsel?
23	which we marked as Exhibit 15; is that right?	23	MS. O'DELL: Objection to form.
24	A. That's correct.	24	A. I didn't I I don't know
	Page 147		Page 149
1	Q. All right. Those studies did	1	that and doesn't matter to me.
2	not involve the perineal application of		
	not involve the permeat application of	2	BY MR. ZELLERS:
3	talcum powder products; is that right?	2 3	BY MR. ZELLERS: Q. Do you know where the data in
3 4			
	talcum powder products; is that right?	3	Q. Do you know where the data in
4	talcum powder products; is that right? MS. O'DELL: Object to the	3 4	Q. Do you know where the data in those exhibits come from?
4 5	talcum powder products; is that right? MS. O'DELL: Object to the form.	3 4 5	Q. Do you know where the data in those exhibits come from?A. Well, they come from the two
4 5 6	talcum powder products; is that right? MS. O'DELL: Object to the form. A. It was not a factor in the	3 4 5 6	Q. Do you know where the data in those exhibits come from? A. Well, they come from the two persons who are testifying who have produced them from their mostly from their business
4 5 6 7	talcum powder products; is that right? MS. O'DELL: Object to the form. A. It was not a factor in the study. BY MR. ZELLERS:	3 4 5 6 7	Q. Do you know where the data in those exhibits come from? A. Well, they come from the two persons who are testifying who have produced them from their mostly from their business records.
4 5 6 7 8	talcum powder products; is that right? MS. O'DELL: Object to the form. A. It was not a factor in the study. BY MR. ZELLERS: Q. Crocidolite and chrysotile	3 4 5 6 7 8	Q. Do you know where the data in those exhibits come from? A. Well, they come from the two persons who are testifying who have produced them from their mostly from their business records.
4 5 6 7 8 9	talcum powder products; is that right? MS. O'DELL: Object to the form. A. It was not a factor in the study. BY MR. ZELLERS: Q. Crocidolite and chrysotile asbestos has generally not been found in	3 4 5 6 7 8 9	 Q. Do you know where the data in those exhibits come from? A. Well, they come from the two persons who are testifying who have produced them from their mostly from their business records. Q. Okay. So you believe that
4 5 6 7 8 9	talcum powder products; is that right? MS. O'DELL: Object to the form. A. It was not a factor in the study. BY MR. ZELLERS: Q. Crocidolite and chrysotile asbestos has generally not been found in talcum powder products, correct?	3 4 5 6 7 8 9	 Q. Do you know where the data in those exhibits come from? A. Well, they come from the two persons who are testifying who have produced them from their mostly from their business records. Q. Okay. So you believe that Exhibit Hopkins-28 to the Hopkins deposition
4 5 6 7 8 9 10	talcum powder products; is that right? MS. O'DELL: Object to the form. A. It was not a factor in the study. BY MR. ZELLERS: Q. Crocidolite and chrysotile asbestos has generally not been found in talcum powder products, correct? A. In general, that's the case.	3 4 5 6 7 8 9 10	 Q. Do you know where the data in those exhibits come from? A. Well, they come from the two persons who are testifying who have produced them from their mostly from their business records. Q. Okay. So you believe that Exhibit Hopkins-28 to the Hopkins deposition and Exhibit Pier-47 to the Pier deposition come from the business records of the
4 5 6 7 8 9 10 11	talcum powder products; is that right? MS. O'DELL: Object to the form. A. It was not a factor in the study. BY MR. ZELLERS: Q. Crocidolite and chrysotile asbestos has generally not been found in talcum powder products, correct? A. In general, that's the case. Q. Was there ever a point in time	3 4 5 6 7 8 9 10 11	Q. Do you know where the data in those exhibits come from? A. Well, they come from the two persons who are testifying who have produced them from their mostly from their business records. Q. Okay. So you believe that Exhibit Hopkins-28 to the Hopkins deposition and Exhibit Pier-47 to the Pier deposition come from the business records of the Johnson & Johnson Company and Imerys?
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4 5 6 7 8 9 10 11 12 13 14 15	talcum powder products; is that right? MS. O'DELL: Object to the form. A. It was not a factor in the study. BY MR. ZELLERS: Q. Crocidolite and chrysotile asbestos has generally not been found in talcum powder products, correct? A. In general, that's the case. Q. Was there ever a point in time where you believe that the talcum powder products involved in this case were not	3 4 5 6 7 8 9 10 11 12 13	Q. Do you know where the data in those exhibits come from? A. Well, they come from the two persons who are testifying who have produced them from their mostly from their business records. Q. Okay. So you believe that Exhibit Hopkins-28 to the Hopkins deposition and Exhibit Pier-47 to the Pier deposition come from the business records of the Johnson & Johnson Company and Imerys? A. From the most part, there was a there was a table that was constructed
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4 5 6 7 8 9 10 11 12 13 14 15 16 17	talcum powder products; is that right? MS. O'DELL: Object to the form. A. It was not a factor in the study. BY MR. ZELLERS: Q. Crocidolite and chrysotile asbestos has generally not been found in talcum powder products, correct? A. In general, that's the case. Q. Was there ever a point in time where you believe that the talcum powder products involved in this case were not contaminated with asbestos? MS. O'DELL: Objection to form,	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	Q. Do you know where the data in those exhibits come from? A. Well, they come from the two persons who are testifying who have produced them from their mostly from their business records. Q. Okay. So you believe that Exhibit Hopkins-28 to the Hopkins deposition and Exhibit Pier-47 to the Pier deposition come from the business records of the Johnson & Johnson Company and Imerys? A. From the most part, there was a there was a table that was constructed during the deposition which was sort of a piece of summary information. I don't know
4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	talcum powder products; is that right? MS. O'DELL: Object to the form. A. It was not a factor in the study. BY MR. ZELLERS: Q. Crocidolite and chrysotile asbestos has generally not been found in talcum powder products, correct? A. In general, that's the case. Q. Was there ever a point in time where you believe that the talcum powder products involved in this case were not contaminated with asbestos? MS. O'DELL: Objection to form, vague as to time.	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	Q. Do you know where the data in those exhibits come from? A. Well, they come from the two persons who are testifying who have produced them from their mostly from their business records. Q. Okay. So you believe that Exhibit Hopkins-28 to the Hopkins deposition and Exhibit Pier-47 to the Pier deposition come from the business records of the Johnson & Johnson Company and Imerys? A. From the most part, there was a there was a table that was constructed during the deposition which was sort of a piece of summary information. I don't know if it's an exhibit to the deposition or if
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38 (Pages 146 to 149)

	Page 150		Page 152
1	Exhibit Hopkins-28 and Pier	1	exhibits you're looking at,
2	Exhibit Pier-47 in answering these	2	Exhibit Hopkins-28 and Exhibit Pier-47, were
3	questions?	3	included in talcum powder product sold by J&J
4	THE WITNESS: If that's easy to	4	Consumer Products?
5	do, yes.	5	MS. O'DELL: Objection to the
6	MS. O'DELL: It's very easy to	6	form, asked and answered.
7	do. This is a copy of	7	A. No, I don't.
8	Exhibit Hopkins-28 of the Hopkins	8	BY MR. ZELLERS:
9	deposition and Exhibit Pier-47 of the	9	Q. Have you confirmed strike
10	Pier deposition.	10	that.
11	THE WITNESS: Okay.	11	What amount of asbestos
12	BY MR. ZELLERS:	12	exposure is associated with ovarian cancer?
13	Q. Dr. Carson?	13	A. Any.
14	A. Yes, sir.	14	Q. Your testimony under oath is
15	Q. Did you make any effort to	15	that any asbestos exposure is associated with
16	investigate the alternative explanations for	16	ovarian cancer?
17	the data that's contained in those two	17	A. Any asbestos exposure and any
18	exhibits, Exhibit Hopkins-28 and	18	perineal application of talcum powder is
19	Exhibit Pier-47?	19	associated with an increased risk for ovarian
20	A. Alternative explanations, I'm	20	cancer.
21	not sure what you mean by that.	21	Q. The amount of asbestos
22	Q. If the Johnson & Johnson	22	contained or allegedly contained within
23	company companies' scientists and Imerys'	23	the baby powder is of no consequence,
24	scientists opined that those tests don't	24	correct?
	Page 151		
1	actually show asbestos, you have no expertise	1	MS. O'DELL: Object to the
1 2	actually show asbestos, you have no expertise to dispute that, do you?	1 2	
			MS. O'DELL: Object to the
2	to dispute that, do you?	2	MS. O'DELL: Object to the form.
2	to dispute that, do you? MS. O'DELL: Object to the	2 3	MS. O'DELL: Object to the form. A. No, it is of consequence, and a
2 3 4	to dispute that, do you? MS. O'DELL: Object to the form.	2 3 4	MS. O'DELL: Object to the form. A. No, it is of consequence, and a larger dose would be a greater hazard. But
2 3 4 5	to dispute that, do you? MS. O'DELL: Object to the form. A. No, I don't have any personal	2 3 4 5	MS. O'DELL: Object to the form. A. No, it is of consequence, and a larger dose would be a greater hazard. But that doesn't mean that a low dose is not a
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2 3 4 5 6 7	to dispute that, do you? MS. O'DELL: Object to the form. A. No, I don't have any personal expertise to dispute that. BY MR. ZELLERS:	2 3 4 5 6 7	MS. O'DELL: Object to the form. A. No, it is of consequence, and a larger dose would be a greater hazard. But that doesn't mean that a low dose is not a hazard. BY MR. ZELLERS:
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	Page 154		Page 156
1	asbestos can produce all types of ovarian	1	A. That's background information
2	cancer; is that correct?	2	and my personal knowledge.
3	MS. O'DELL: Object to the	3	Q. You are not going to give an
4	form.	4	opinion on mines, mining or milling in this
5	A. I suspect that some forms of	5	case; is that right?
6	asbestos are much more carcinogenic than	6	A. Depends on the questions.
7	others, and that would be true for the	7	Q. Well, as you sit here today, do
8	ovaries as well as other structures in the	8	you intend to give opinions on talc mining,
9	body.	9	mines or milling?
10	BY MR. ZELLERS:	10	A. It wasn't my intention, but if
11	Q. Are you able to distinguish for	11	asked a question that I think I'm qualified
12	us what types of asbestos cause or are	12	to answer, I'll try to do it.
13	associated with what types of ovarian cancer?	13	Q. Are you an expert on talc
14	A. I don't think I'm able to make	14	mining and milling?
15	those distinctions, but the studies I just	15	A. I'm an expert on industrial
16	read to you regarding the relationship	16	processes in general, and if I have some
17	between asbestos and ovarian cancer and the	17	•
18	others on my list do indicate that there are,	18	personal understanding of talc mining and milling.
19		19	•
20	for example, in the Acheson study, there	1	Q. Have you been personally
	were there was a positive relationship	20	involved in talc mining and milling?
21	between both crocidolite and chrysotile	21	A. I haven't been involved in it;
22	exposure, and the crocidolite had a greater	22	I've observed it.
23	effect on ovarian cancer than the chrysotile,	23	Q. Do you consider yourself to be
24	but did not have they were both positive.	24	an expert in talc mining and milling?
	Page 155		Page 157
1	Q. What type of ovarian cancer?	1	MS. O'DELL: Objection, asked
2	A. That, I don't know at the	2	and answered.
3	moment. I could look in the paper and see if	3	A. No, I don't.
4	it's listed.	4	BY MR. ZELLERS:
5	Q. There are a number of different	5	Q. You have no independent basis
6	types of ovarian cancer; is that right?		
7	,	1 0	to say that cosmetic talc contains asbestos.
	A. That's correct.	6 7	to say that cosmetic talc contains asbestos, correct?
	A. That's correct. O You are not familiar with I&I	7	correct?
8	Q. You are not familiar with J&J	7 8	correct? MS. O'DELL: Object to the
8 9	Q. You are not familiar with J&J Consumer Products' procedures for milling or	7 8 9	correct? MS. O'DELL: Object to the form.
8 9 10	Q. You are not familiar with J&J Consumer Products' procedures for milling or mining; is that right?	7 8 9 10	correct? MS. O'DELL: Object to the form. A. What do you mean by independent
8 9 10 11	Q. You are not familiar with J&J Consumer Products' procedures for milling or mining; is that right? MS. O'DELL: Object to the	7 8 9 10 11	correct? MS. O'DELL: Object to the form. A. What do you mean by independent basis?
8 9 10 11 12	Q. You are not familiar with J&J Consumer Products' procedures for milling or mining; is that right? MS. O'DELL: Object to the form.	7 8 9 10 11 12	correct? MS. O'DELL: Object to the form. A. What do you mean by independent basis? BY MR. ZELLERS:
8 9 10 11 12 13	Q. You are not familiar with J&J Consumer Products' procedures for milling or mining; is that right? MS. O'DELL: Object to the form. A. I'm familiar with some of their	7 8 9 10 11 12 13	correct? MS. O'DELL: Object to the form. A. What do you mean by independent basis? BY MR. ZELLERS: Q. You have not done any testing
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8 9 10 11 12 13 14 15 16 17	Q. You are not familiar with J&J Consumer Products' procedures for milling or mining; is that right? MS. O'DELL: Object to the form. A. I'm familiar with some of their procedures, yes. BY MR. ZELLERS: Q. Are you familiar with their testing of source mines? A. To some extent.	7 8 9 10 11 12 13 14 15 16 17	correct? MS. O'DELL: Object to the form. A. What do you mean by independent basis? BY MR. ZELLERS: Q. You have not done any testing of talcum powder to determine whether it contains asbestos or not; is that right? A. No. All of my understanding is based on other sources. Q. And those other sources would
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8 9 10 11 12 13 14 15 16 17 18 19 20	Q. You are not familiar with J&J Consumer Products' procedures for milling or mining; is that right? MS. O'DELL: Object to the form. A. I'm familiar with some of their procedures, yes. BY MR. ZELLERS: Q. Are you familiar with their testing of source mines? A. To some extent. MS. O'DELL: Object to the form.	7 8 9 10 11 12 13 14 15 16 17 18 19 20	orrect? MS. O'DELL: Object to the form. A. What do you mean by independent basis? BY MR. ZELLERS: Q. You have not done any testing of talcum powder to determine whether it contains asbestos or not; is that right? A. No. All of my understanding is based on other sources. Q. And those other sources would be, in part, the testing that was done by Longo; is that right?
8 9 10 11 12 13 14 15 16 17 18 19 20 21	Q. You are not familiar with J&J Consumer Products' procedures for milling or mining; is that right? MS. O'DELL: Object to the form. A. I'm familiar with some of their procedures, yes. BY MR. ZELLERS: Q. Are you familiar with their testing of source mines? A. To some extent. MS. O'DELL: Object to the form. BY MR. ZELLERS:	7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	orrect? MS. O'DELL: Object to the form. A. What do you mean by independent basis? BY MR. ZELLERS: Q. You have not done any testing of talcum powder to determine whether it contains asbestos or not; is that right? A. No. All of my understanding is based on other sources. Q. And those other sources would be, in part, the testing that was done by Longo; is that right? A. Yes, as well as the testing
8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q. You are not familiar with J&J Consumer Products' procedures for milling or mining; is that right? MS. O'DELL: Object to the form. A. I'm familiar with some of their procedures, yes. BY MR. ZELLERS: Q. Are you familiar with their testing of source mines? A. To some extent. MS. O'DELL: Object to the form. BY MR. ZELLERS: Q. Is it set forth in your report,	7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	orrect? MS. O'DELL: Object to the form. A. What do you mean by independent basis? BY MR. ZELLERS: Q. You have not done any testing of talcum powder to determine whether it contains asbestos or not; is that right? A. No. All of my understanding is based on other sources. Q. And those other sources would be, in part, the testing that was done by Longo; is that right? A. Yes, as well as the testing that's reported in the — in the literature
8 9 10 11 12 13 14 15 16 17 18 19 20 21	Q. You are not familiar with J&J Consumer Products' procedures for milling or mining; is that right? MS. O'DELL: Object to the form. A. I'm familiar with some of their procedures, yes. BY MR. ZELLERS: Q. Are you familiar with their testing of source mines? A. To some extent. MS. O'DELL: Object to the form. BY MR. ZELLERS:	7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	orrect? MS. O'DELL: Object to the form. A. What do you mean by independent basis? BY MR. ZELLERS: Q. You have not done any testing of talcum powder to determine whether it contains asbestos or not; is that right? A. No. All of my understanding is based on other sources. Q. And those other sources would be, in part, the testing that was done by Longo; is that right? A. Yes, as well as the testing

40 (Pages 154 to 157)

	Arch I. "Chip" Ca	<i>x</i> 1 5011	, 11.5., 111.5.
	Page 158		Page 160
1	Q. You're looking now back at the	1	BY MR. ZELLERS:
2	Pier Exhibit Pier-47 and the Hopkins	2	Q. The Reid paper that I've handed
3	Exhibit Hopkins-28; is that right?	3	you, what we've marked as Exhibit 17, looks
4	A. I was actually referring to the	4	at the issue: Does exposure to asbestos
5	Imerys documents that are referenced toward	5	cause ovarian cancer.
6	the end of the literature exhibit to my	6	Is that right?
7	report, but certainly the Exhibit Pier-47	7	A. Yes.
8	would be included there.	8	Q. They talk about in terms of
9	Q. You have no independent basis	9	limitations on the first page, right-hand
10	to say that cosmetic talcum powder contains	10	column, they say: Studies that have examined
11	fibrous tale, correct?	11	this issue have been limited for two major
12	MS. O'DELL: Object to the	12	reasons.
13	form.	13	Is that right?
14	A. I have no independent basis,	14	A. Yes.
15	no.	15	Q. Number one, small number of
16	BY MR. ZELLERS:	16	cases, much fewer women than men have been
17	Q. You're familiar with the	17	exposed to asbestos, particularly in more
18	limitations of the research on a potential	18	heavily exposed occupational settings where
19	*	19	relative risks are higher; is that right?
20	link between asbestos and ovarian cancer; is	20	A. Yes.
21	that right?	21	
22	MS. O'DELL: Object to the	22	Q. How many of these studies well, strike that.
23	form.	23	•
	A. I'm familiar with some research	24	Would you agree that the
24	limitations in that question, yes.	24	studies in this area have been primarily
	Page 159		Page 161
1	BY MR. ZELLERS:	1	related to occupational exposure?
2	Q. You agree that research on the	2	A. Primarily, yes.
3	potential relationship between asbestos and	3	Q. How many total women have been
4	ovarian cancer has only considered a small	4	studied?
5	number of cases; is that right?	5	MS. O'DELL: Object to the
6	MS. O'DELL: Object to the	6	form. In this study, in this paper,
7	form.	7	or are you talking about in general?
8	A. Well, it's considered thousands	8	MR. ZELLERS: In general.
9	of cases. Certainly in terms of the number	9	A. I don't know the answer to
10	of women who have experienced ovarian cancer	10	that.
11	it's small, but it's significant, and that's	11	BY MR. ZELLERS:
12	where we get research from that answers	12	Q. How many women have been
13	important questions.	13	studied in nonoccupational studies?
14	BY MR. ZELLERS:	14	A. Well, very few in comparison to
15	Q. Are you familiar with the Reid	15	the occupational studies.
16	paper, 2011?	16	Q. Are you aware of the
17	A. Yes, but it's been a while	17	difficulties that have existed over time in
18	since I've looked at it.	18	distinguishing between peritoneal
19	Q. Well, I'll hand you a copy.	19	mesothelioma and ovarian cancer?
20	We'll mark it as Exhibit 17.	20	A. Yes.
21	(Carson Deposition Exhibit 17	21	Q. What are those difficulties?
22	marked.)	22	A. There is a potential
23	MS. O'DELL: Thank you.	23	misclassification of one as the other because
24	///	24	they have very common habits. They look very

41 (Pages 158 to 161)

		1	
	Page 162		Page 164
1	similar under light microscopy, and they're	1	take a minute to refresh yourself on
2	often difficult to distinguish, even by a	2	the page
3	pathologist, unless special tests are used.	3	MR. ZELLERS: I'm looking under
4	Often these cases occur in	4	Discussion.
5	places where they don't have the access to	5	MS. O'DELL: please feel
6	special test equipment that can definitively	6	free to do that.
7	distinguish, and so they are classified and	7	Excuse me, sir, I was talking.
8	we move on.	8	If you need to review the paper,
9	Q. Another limitation of any	9	Dr. Carson, please feel free to do
10	studies in this area relate to the inability	10	that.
11	to account for nonoccupational risk factors	11	MR. ZELLERS: This doctor has
12	for ovarian cancer other than age; is that	12	given 35 depositions. He is perfectly
13	right?	13	capable of handling himself. He does
14	MS. O'DELL: Object to the	14	not need your advice as we go along.
15	form.	15	MS. O'DELL: Nor do I, Michael.
16	A. Are you reading also from this	16	So I'm going to deal with this witness
17	paper or	17	in the way I choose, which is
18	BY MR. ZELLERS:	18	perfectly appropriate. If Dr. Carson
19	Q. I was looking now at the	19	needs to review the paper, he's going
20	Camargo paper. Are you familiar with the	20	to review the paper. You may ask him
21		21	
22	Camargo paper?	22	questions, he'll be happy to respond.
23	A. If you have a copy of that, I'd	23	MR. ZELLERS: Your job is not
24	like to look at it, if I'm going to answer	24	to coach the witness; your job is to
24	questions about it.	24	make objections as to form or
	Page 163		Page 165
1	Q. All right. This is a paper in	1	foundation, not to make speaking
2	2011. We'll mark it as Exhibit 18.	2	objections and coaching of the
3	(Carson Deposition Exhibit 18	3	witness.
4	marked.)	4	MS. O'DELL: If you have a
5	BY MR. ZELLERS:	5	question, I'm sure Dr. Carson would be
6	Q. Here the authors also looked at	6	happy to address it.
7	the issue of occupational exposure to	7	MR. ZELLERS: I've asked him
8	asbestos and ovarian cancer; is that right?	8	the question.
9	A. Yes.	9	MS. O'DELL: Would you mind
10	Q. If you turn to page 216 I'm	10	repeating the question, please?
11	sorry, 1216, second-to-last paragraph before	11	MR. ZELLERS: Sure.
12	the conclusion: A further limitation of our	12	THE WITNESS: I don't remember
13	analysis was its inability to account for	13	the question.
14	nonoccupational risk factors for ovarian	14	MR. ZELLERS: Okay. I'll be
15	cancer other than age.	15	happy to repeat it.
16	Is that identified by the	16	BY MR. ZELLERS:
17	authors as a limitation?	17	Q. Dr. Carson, you've looked at
18	A. Yes, it is.	18	this Camargo paper; is that right?
19	Q. Under if you go a page back,	19	A. Yes.
20	1215, under Discussion, in the second	20	Q. In their discussion, they talk
21	paragraph, the authors talk about other	21	about other research, including research done
22	studies that have been done in this area,	22	by Edelman; is that right?
23	including Edelman; is that right?	23	A. Are you at the top of the
24	MS. O'DELL: If you need to	24	middle column on
	•		

42 (Pages 162 to 165)

	Aren i. enip	,	, M.D., III.D.
	Page 166		Page 168
1	Q. I'm looking under Discussion.	1	BY MR. ZELLERS:
2	A. Yes.	2	Q if your theory is correct?
3	Q. The first well, the second	3	MS. O'DELL: Object to the
4	paragraph.	4	form.
5	A. Second paragraph, yes.	5	A. There may have been higher
6	Q. The magnitude of the pooled	6	rates of ovarian cancers, but you have to
7	estimate is similar to that reported by		also understand that the latency period for
8	Edelman; is that right?	7 8 9	ovarian cancer is pretty long. It's greater
9	A. Correct. Correct.		than 20 years, often as long as 40 years.
10	Q. Then they state: They	10	And so we're still dealing with cancers that
11	concluded, however, that despite the positive	11	may have started back in the '70s.
12	and significant association, there was	12	BY MR. ZELLERS:
13	insufficient information to infer that	13	
14		14	Q. Would you agree that exposure
14 15	ovarian cancers were caused by occupational	15	to asbestos through a perineal cosmetic talc
	exposure to asbestos because of concerns		use is different from the heavy occupational
16	about tumor misclassification, inappropriate	16	exposure that has primarily been researched?
17	comparison populations and the failure to	17	MS. O'DELL: Objection to form.
18	take into account for known risk factors.	18	A. Yes. I agree with that.
19	Did I read that	19	BY MR. ZELLERS:
20	A. You read that correctly.	20	Q. Are you an expert and
21	Q. All right. Are women who use	21	knowledgeable about cleavage fragments?
22	talc perineally at greater risk of	22	A. I'm not.
23	mesothelioma?	23	Q. If I went through a series of
24	A. I can't say that they are, but	24	questions and asked you to differentiate
	Page 167		Page 169
1	they may be.	1	between cleavage fragments and asbestos
2	Q. Wouldn't you expect to find	2	fibers, you would defer that to other
3	higher rates of other cancers in women using	3	experts?
4	talc like mesothelioma if they are being	4	A. I would.
5	exposed to substantial amounts of asbestos?	5	Q. You also claim that the
6	A. Well, we may we may be	6	presence of carcinogenic metals, including
7	seeing some mesotheliomas that are	7	chromium, cobalt and nickel in tale, adds to
8	misclassified as ovarian cancers, or we may	8	its carcinogenicity; is that right?
9	be seeing mesotheliomas and not relating talc	9	A. That is right.
10	application as a pertinent contributor to	10	Q. Do you have an opinion or
11	that case.	11	knowledge as to the amounts of chromium,
12	Q. You told us earlier that you	12	cobalt and nickel, if any, in talc?
13	thought that there may have been more	13	A. Those metal elements are
14	asbestos in talcum powders in the 1970s; is	14	included as usually as impurities or in
15	that right?	15	very small quantities in some deposits and
16	MS. O'DELL: Objection to form.	16	are present in small amounts.
17	A. I think I said there have been	17	Q. Do you have any idea how much
18	step-wise improvements, and I but I agree	18	of these metals, if any, reaches a woman's
19		19	
1 7	with that statement. BY MR. ZELLERS:	20	ovaries each time they use talc?
		∠∪	A. I can't tell you how much, but
20		21	I can tall you that came dose and it is
20 21	Q. Shouldn't we have seen higher	21	I can tell you that some does, and it is
20 21 22	Q. Shouldn't we have seen higher rates of ovarian cancer in the earlier	22	it remains in the talc until long after it
20 21 22 23	Q. Shouldn't we have seen higher rates of ovarian cancer in the earlier studies	22 23	it remains in the talc until long after it reaches the ovaries.
20 21 22	Q. Shouldn't we have seen higher rates of ovarian cancer in the earlier	22	it remains in the talc until long after it

43 (Pages 166 to 169)

	Alch i. chip		
	Page 170		Page 172
1	natural elements; is that right?	1	to chromium, cobalt or nickel or any other
2	A. Yes.	2	heavy metal; is that right?
3	Q. They are naturally in our	3	A. That is correct.
4	bodies; is that right?	4	Q. That answer to that question
5	A. That's correct.	5	would be true if I asked you about the
6	Q. They are present in food,	6	different fragrance chemicals, correct?
7	drinking water, bottled water, vitamins; is	7	MS. O'DELL: Object to the
8	that right?	8	form.
9	A. To some extent.	9	A. Also true.
10	Q. Do you have any evidence that	10	BY MR. ZELLERS:
11	the blood or tissue levels of any trace heavy	11	Q. You did a risk assessment in
12	metals are higher in genital talc users	12	this matter; is that right?
13	compared to nonusers?	13	A. Yes.
14	MS. O'DELL: Object to the	14	Q. Do you agree that a complete
15	form.	15	and proper risk assessment involves four
16	A. I do not.	16	
17	A. 1 do not. BY MR. ZELLERS:		elements?
18		17 18	MS. O'DELL: Object to the
	Q. As we discussed when we talked		form.
19	about asbestos, you cannot evaluate the	19	A. Not necessarily.
20	potential effects of exposure to a substance	20	BY MR. ZELLERS:
21	without factoring in the amount of exposure;	21	Q. Well, you have to identify a
22	is that right?	22	potential hazard; is that right?
23	MS. O'DELL: Object to the	23	A. Yes.
24	form.	24	Q. You've got to do some type of
	Page 171		Page 173
1	A. It's useful to factor in the	1	dose-response assessment; is that right?
2	amount if the amount is known. If the amount	1 2 3 4 5 6 7	A. Not necessarily.
3	is not known, it's not necessarily required	3	Q. You
4	to draw conclusions.	4	MS. O'DELL: Excuse me. If you
5	BY MR. ZELLERS:	5	finished if you need to,
6	Q. In this case, you do not know	6	Dr. Carson, if you're not finished.
7	the amount, be it chromium, cobalt and/or	7	If you're finished, fine. Sorry.
8	nickel; is that right?	8	A. A qualitative risk assessment
9	MS. O'DELL: Objection to the	9	does not necessarily require a dose-response
10	form.	10	in order to reach valid conclusions.
11	Excuse me. Dr. Carson, as you	11	BY MR. ZELLERS:
12	know, is not being offered as a	12	Q. It is not necessary to do a
13	case-specific expert, so that question	13	dose-response assessment as part of a risk
14	sounds like a specific patient, and so	14	assessment. Is that your testimony under
15	I would that's my objection.	15	oath?
16	A. I do not know the amount, but	16	A. It's not always necessary.
17	my opinion is that any within the	17	Q. Was it necessary in this case?
	microenvironment of the inflammatory process	18	A. Well, I think there is an
18		19	aspect of dose-response that was performed in
18 19	· ·		
19	that is occurring due to talc sequestration		
19 20	that is occurring due to talc sequestration is contributing to the carcinogenic	20	the risk assessment process here.
19 20 21	that is occurring due to talc sequestration is contributing to the carcinogenic potential.	20 21	the risk assessment process here. Q. What dose-response assessment
19 20 21 22	that is occurring due to talc sequestration is contributing to the carcinogenic potential. BY MR. ZELLERS:	20 21 22	the risk assessment process here. Q. What dose-response assessment did you make with respect to chromium, cobalt
19 20 21	that is occurring due to talc sequestration is contributing to the carcinogenic potential.	20 21	the risk assessment process here. Q. What dose-response assessment

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Page 174		Page 17
available to do a dose-response estimate for	1	and the metals were there as the baseline
those metals.	2	component of the talc formation that they
Q. What information did you rely	2 3	came from.
or use, if any, to make a dose-response	4	BY MR. ZELLERS:
assessment with respect to any fragrance	5	Q. You do not know the amounts of
chemicals?	6	either the heavy metals or the fragrance
MS. O'DELL: Objection, form.	7	chemicals in the talcum powder at issue in
A. There is no information	8	this case, correct?
available to do a dose-response estimate for	9	A. That's that's correct, I
the fragrances.	10	don't.
BY MR. ZELLERS:	11	Q. You do not know well, strike
Q. Did you do any type of exposure	12	that. I'll withdraw that.
assessment in this case?	13	You brought with you an IARC
MS. O'DELL: Object to the	14	monograph; is that right?
form, vague.	15	A. I have a couple of them.
A. I'm not sure exactly what	16	Q. All right.
you're what you're asking by exposure	17	MS. O'DELL: Are we going to
assessment.	18	are you going to move to
BY MR. ZELLERS:	19	MR. ZELLERS: We can take a
Q. Well, an exposure assessment is	20	break if you'd like.
also part of a risk assessment; is that	21	MS. O'DELL: Yeah, it's been
	22	about an hour and a half.
right? A. In this risk assessment, I	23	MR. ZELLERS: Sure.
	24	THE VIDEOGRAPHER: We're o
considered studies that are reported in the	24	THE VIDEOURAPHER. WE'VE OF
Page 175		Page 17
scientific and medical literature which have	1	the record 12:32, end of Tape 2.
reported the assessment of exposure in these	2	(Recess taken, 12:32 p.m. to
cases in various forms, and I considered	3	1:38 p.m.)
cases in various forms, and I considered those exposure assessments as being valid as		± '
	3	- ·
those exposure assessments as being valid as	3 4	THE VIDEOGRAPHER: We're on the
those exposure assessments as being valid as reported and considered them as a whole. Q. Did you look at any exposure	3 4 5	THE VIDEOGRAPHER: We're on the record, 1:38, beginning of Tape 3. BY MR. ZELLERS:
those exposure assessments as being valid as reported and considered them as a whole.	3 4 5 6	THE VIDEOGRAPHER: We're on the record, 1:38, beginning of Tape 3. BY MR. ZELLERS:
those exposure assessments as being valid as reported and considered them as a whole. Q. Did you look at any exposure assessment specific to the alleged heavy	3 4 5 6 7	THE VIDEOGRAPHER: We're on the record, 1:38, beginning of Tape 3. BY MR. ZELLERS: Q. Dr. Carson, when we left, we
those exposure assessments as being valid as reported and considered them as a whole. Q. Did you look at any exposure assessment specific to the alleged heavy metals contained in talcum powder?	3 4 5 6 7 8	THE VIDEOGRAPHER: We're on the record, 1:38, beginning of Tape 3. BY MR. ZELLERS: Q. Dr. Carson, when we left, we were talking about the trace metals and
those exposure assessments as being valid as reported and considered them as a whole. Q. Did you look at any exposure assessment specific to the alleged heavy metals contained in talcum powder? MS. O'DELL: Object to the	3 4 5 6 7 8	THE VIDEOGRAPHER: We're on the record, 1:38, beginning of Tape 3. BY MR. ZELLERS: Q. Dr. Carson, when we left, we were talking about the trace metals and fragrance chemicals in talcum powder,
those exposure assessments as being valid as reported and considered them as a whole. Q. Did you look at any exposure assessment specific to the alleged heavy metals contained in talcum powder? MS. O'DELL: Object to the form.	3 4 5 6 7 8 9	THE VIDEOGRAPHER: We're on the record, 1:38, beginning of Tape 3. BY MR. ZELLERS: Q. Dr. Carson, when we left, we were talking about the trace metals and fragrance chemicals in talcum powder, correct? A. Yes.
those exposure assessments as being valid as reported and considered them as a whole. Q. Did you look at any exposure assessment specific to the alleged heavy metals contained in talcum powder? MS. O'DELL: Object to the form. A. No, I did not. BY MR. ZELLERS:	3 4 5 6 7 8 9 10	THE VIDEOGRAPHER: We're on the record, 1:38, beginning of Tape 3. BY MR. ZELLERS: Q. Dr. Carson, when we left, we were talking about the trace metals and fragrance chemicals in talcum powder, correct? A. Yes. Q. You do not know how much of
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those exposure assessments as being valid as reported and considered them as a whole. Q. Did you look at any exposure assessment specific to the alleged heavy metals contained in talcum powder? MS. O'DELL: Object to the form. A. No, I did not. BY MR. ZELLERS: Q. Did you look at any exposure assessment with respect to any fragrance	3 4 5 6 7 8 9 10 11 12 13	THE VIDEOGRAPHER: We're on the record, 1:38, beginning of Tape 3. BY MR. ZELLERS: Q. Dr. Carson, when we left, we were talking about the trace metals and fragrance chemicals in talcum powder, correct? A. Yes. Q. You do not know how much of these trace metals or fragrance chemicals reach the ovaries, correct?
those exposure assessments as being valid as reported and considered them as a whole. Q. Did you look at any exposure assessment specific to the alleged heavy metals contained in talcum powder? MS. O'DELL: Object to the form. A. No, I did not. BY MR. ZELLERS: Q. Did you look at any exposure assessment with respect to any fragrance chemicals contained within talcum powder?	3 4 5 6 7 8 9 10 11 12 13 14 15	THE VIDEOGRAPHER: We're on the record, 1:38, beginning of Tape 3. BY MR. ZELLERS: Q. Dr. Carson, when we left, we were talking about the trace metals and fragrance chemicals in talcum powder, correct? A. Yes. Q. You do not know how much of these trace metals or fragrance chemicals reach the ovaries, correct? A. I don't know specifically how
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	Arch 1. "Chip" Ca		,
	Page 178		Page 180
1	Q. You do not know the exposure of	1	BY MR. ZELLERS:
2	any of the women who are plaintiffs in this	2	Q. What would you agree that,
3	litigation to the talcum powder, correct?	3	in general, metals can differ in their
4	MS. O'DELL: Individual women?	4	toxicity and potential carcinogenicity based
5	MR. ZELLERS: Yes, individual	5	on their form?
6	women.	6	A. Yes.
7	A. I don't, no.	7	Q. Do you know the forms of
8	BY MR. ZELLERS:	8	chromium, nickel and cobalt detected in
9	Q. You brought with you an IARC	9	cosmetic tale?
10	monograph, and I think you've got several	10	A. There's metal ions are
11	monographs that are on your literature list;	11	usually incorporated in the mineral lattice,
12	is that right?	12	and so they are part of the magnesium
13	A. That's correct.	13	silicate crystal.
14	Q. Generally, IARC classifies	14	Q. I'm not sure if that answers my
15	chemicals and agents from Group 1,	15	question, and if it does, I don't understand,
16	carcinogenic to humans, down to Group 4,	16	so let me ask again.
17	probably not carcinogenic to humans; is that	17	e e
18		18	Do you know the forms, and by
	right?		that I mean valence state, of chromium or
19	A. That's correct.	19	nickel or cobalt that have been detected in
20	Q. Does the classification of a	20	cosmetic tale?
21	substance as a known probable or possible	21	A. Oh, the valence state?
22	carcinogen by IARC, and IARC is International	22	Q. Yes, sir.
23	Agency for Research on Cancer, or by the	23	A. I don't know specifically, but
24	National Toxicology Program or the U.S.	24	that's dependent on the surrounding structure
	Page 179		Page 181
1	Environmental Protection Agency, mean that	1	that the metals are contained in, and metals
2	the substance can cause all types of cancers	2	can assume a different valence state
3	in humans by any exposure route?	3	depending on the redox environment.
4	MS. O'DELL: Object to the	4	Q. You are not, at least in this
5	form.	5	litigation today, expressing any opinion as
6	A. No.	6	to the valence state of chromium that may be
7	BY MR. ZELLERS:	7	found in cosmetic tale, correct?
8	Q. There are different cancers	8	MS. O'DELL: Object to the
9	that may be associated with different	9	form.
10	chemicals or agents; is that right?	10	A. No, I'm not.
11	A. And different routes of	11	BY MR. ZELLERS:
12	exposure.	12	Q. Your second opinion is that the
13	Q. You can have an agent that is a	13	perineal use of talcum powder results in
14	carcinogen or a probable or possible	14	direct exposure to the ovaries either via
15	carcinogen for one type of cancer, but not	15	inhalation or migration through the female
16	for another type of cancer, correct?	16	reproductive tract; is that right?
17	A. That's correct.	17	A. Well, it's primarily through
18	Q. You can have an agent or a	18	the female reproductive tract. The
19	chemical that's a carcinogen for one route of	19	-
20		1	inhalation exposure would be a secondary
	exposure for a chemical or agent but is not	20	route.
21	carcinogenic for a different route of	21	Q. Let me ask you a couple of
22	exposure, correct?	22	questions about inhalation exposure.
23	MS. O'DELL: Objection to form.	23	You do not cite any studies in
24	A. Yes.	24	the body of your report evidencing that

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	Page 182		Page 184
1	talcum powder can reach the ovaries through	1	A. The I'm sorry. The Heller
2	inhalation, correct?	2	study was tale, which I didn't cite here.
3	MS. O'DELL: Object to the	3	Halme was a retrograde menstruation study via
4	form.	4	the fallopian tubes, and Sjösten was starch
5	A. That is correct, although	5	particles.
6	there yes, that's correct.	6	Q. The only study and this is
7	BY MR. ZELLERS:	7	not one that you cited, but you've now
8	Q. You have never performed any	8	referred to that involved talc, was Heller;
9	study yourself pertaining to whether inhaled	9	is that right?
10	talc can migrate to the ovaries; is that	10	A. Well, it looked at it didn't
11	right?	11	look at transport inasmuch as it looked at
12	A. I have not, although it has	12	the presence of talc particles in the ovaries
13	been used as an explanation of how talc	13	and found them with or without the history of
14	particles might have reached the ovaries in	14	talc powder use.
15	persons who did not have another form of	15	Q. Heller looked at 24 patients;
16	exposure.	16	is that right?
17	Q. If inhalation is the exposure	17	A. I don't know, but that sounds
18	path for talc, shouldn't the lungs bear more	18	about right.
19	of a burden?	19	Q. Half of them had a history of
20	A. Yes.	20	using talc products, half did not?
21	Q. Why, then, isn't there an	21	MS. O'DELL: Object to form.
22	epidemic of mesothelioma in women who use	22	A. That's correct.
23	talcum powder?	23	BY MR. ZELLERS:
24	A. Because the primary route is	24	Q. Heller found talc in the
	Page 183		Page 185
1	perineal via the reproductive tract.	1	tissues of all 24 patients; is that right?
2	Q. You discuss that on page 7 of	2	A. That is correct.
3	your report; is that right?	3	Q. I believe we covered this
4	A. Yes.	4	before, but just to confirm: There are no
5	Q. You cite a number of studies	5	published articles that you're aware of that
6	for the proposition that talc can be	6	show granulomas, fibrosis or adhesions
7	transported from the perineum to the upper	7	anywhere in the reproductive tract of a woman
8	reproductive tract and body cavity; is that	8	as a result of external genital talc
9	right?	9	application, correct?
10	A. That's correct.	10	MS. O'DELL: Object to the
11	Q. None of the articles that you	11	form.
12	cite actually looked at whether talc can	12	A. I believe that's the case,
13	migrate from perineal application through the	13	although there have been granulomas found in
14	fallopian tubes to the ovaries, did they?	14	some cases of cancer where they reported
15	A. Let me just refresh my memory	15	having used talc.
16	for a moment here. Egli was carbon black.	16	BY MR. ZELLERS:
17	Venter was radioactive technetium labeled	17	Q. Of the cases or the studies you
18	albumin. Let me see. Blumenkrantz I have	18	cited here, Egli, that involved just three
19	my notes here.	19	women, correct?
	Yeah, I can't remember what the	20	A. That was just that was an
20		21	experimental study of the transport of carbon
21	substance was in Blumenkrantz. Sjösten,	I	
21 22	starch yeah, Blumenkrantz was retrograde	22	particles.
21	•	I	

47 (Pages 182 to 185)

	Page 186		Page 188
1	A. That's correct.	1	of all these studies that they were using
2	Q. And that means that they had	2	various particles that could be detected at
3	their legs up in the air, correct?	3	the other end, and so this was an attempt to
4	A. Correct.	4	do an experimental study which would cause no
5	Q. Those conditions well,	5	harm that would give them an answer regarding
6	strike that.	6	transport through the reproductive tract.
7	They were injected with	7	Q. In this study, particles were
8	oxytocin; is that right?	8	introduced into the reproductive tract, not
9	A. It is.	9	externally; is that right?
10	Q. That was to aid in the	10	MS. O'DELL: Object to the
11	transport of the particles, correct?	11	form.
12	MS. O'DELL: Object to the	12	A. That is correct.
13	form.	13	BY MR. ZELLERS:
14	A. I believe that was the author's	14	Q. Women were given Pitocin to
15	theory.	15	stimulate uterine contractions; is that
16	BY MR. ZELLERS:	16	right?
17	O. Those are different	17	A. That's the same as oxytocin.
18	circumstances or conditions from a woman who	18	Q. And that's a yes, correct?
19	would apply a talc to her genital area	19	A. Yes.
20	standing up, correct?	20	Q. Again, as with the Egli study,
21	A. Well, they are, but I'm not	21	the women were inverted in the Trendelenburg
22	sure that that position is really pertinent	22	position with their head down, legs up when
23	to the migration of particles through the	23	the particles were administered; is that
24	reproductive tract.	24	right?
21	reproductive tract.		rigin.
	Page 187		Page 189
1	Q. Is it your pos is it your	1	A. I believe so.
2	testimony that if a woman is in a lithotomy	2	Q. Is it possible that the
3	position with their legs up into the air,	3	radionuclides can leach from the particles?
4	that that is comparable with respect to the	4	A. I don't know the answer to
5	migration of talc to a woman who's standing	5	that, but it was radioactive technetium that
6	up and using it in her perineal region?	6	was bound to albumin.
7	A. It may be.	7	Q. The Sjösten study that you
8	Q. Are you an expert on that?	8	cite, that did not use involve the
9	A. I'm not.	9	perineal use of talc, but an exam with a
10	Q. The authors in Egli, they	10	force to the cervix; is that right?
11	stated it was possible that the study	11	A. Excuse me. An exam with what?
12	observed false positives due to sample	12	Q. So it involved an exam with
13	contamination because they failed to use	13	force to the cervix?
14	liquid or filter blanks as negative controls,	14	MS. O'DELL: Object to the
15	correct?	15	form.
16	A. I don't recall that, but that	16	A. Well, this was this was done
17	may be the case.	17	as an experimental study on women who were
18	Q. You refer to a study by Venter.	18	scheduled to get hysterectomies and they did
19	That involved a radioactive particulate	19	it on some women one day prior to the
20	matter, correct?	20	hysterectomy and another group of women four
21	A. Yes.	21	days prior to the hysterectomy, and they used
22	Q. Did not involve talc particles,	22	gloves that were powdered with starch and
23	correct?	23	gloves that were not powdered with starch.
	331100.	د ک	groves that were not powdered with staten.
24	A. The point of the study was	24	And so they had what's called a

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	Page 190		Page 192
1	Latin square design, and they were able at	1	Q. In fact, in Terry well, and
2	the point of the hysterectomy of taking	2	let me mark it for you so you've got it in
3	samples of the fallopian tubes and washing	3	front of you.
4	them to determine whether or not particles	4	THE WITNESS: Okay. I'm going
5	were found in the tubes.	5	to move this binder for the time
6	BY MR. ZELLERS:	6	being, if you don't mind.
7	Q. What they actually found was	7	MR. ZELLERS: Oh, yes, I'll
8	that, whether the women were examined with	8	hand you the articles that I refer to,
9	gloves with the starch particles or not, they	9	but if you need it, just pull it out.
10	found starch particles in both, both groups,	10	THE WITNESS: Thank you.
11	correct?	11	(Carson Deposition Exhibit 19
12	A. It is true.	12	marked.)
13		13	BY MR. ZELLERS:
		14	
14	tubal ligation and use that or purport to say	1	Q. Deposition Exhibit 19 is the
15	that that supports your migration theory,	15	2013 Terry meta-analysis that you referred to
16	correct?	16	in your report; is that right?
17	A. It does.	17	A. Yes.
18	Q. Your testimony is that for	18	Q. That's a pooled analysis of
19	patients who have had a tubal ligation, that	19	eight studies; is that right?
20	they are at a lesser risk of the talc let	20	A. Yes.
21	me withdraw that.	21	Q. Okay. This pooled analysis of
22	Explain to us very briefly why	22	eight studies relating to genital powder use
23	you believe that tubal ligation supports your	23	and the risk of ovarian cancer shows no
24	migration theory.	24	variation in the risk in talc users based on
	Page 191		Page 193
1	A. If the pathway of exposure of	1	whether they had a tubal ligation or
2	the ovaries that results in ovarian cancer is	2	hysterectomy; is that right?
3	via the reproductive tract, then tubal	3	A. I think that's the conclusion
4	ligation, which closes off the fallopian	4	of the authors here, but it's not the
5			of the authors here, but it's not the
	tubes, would interrupt that pathway and	5	conclusion of the individual authors of the
6	tubes, would interrupt that pathway and result in reduced exposure; therefore, you		conclusion of the individual authors of the
6 7	result in reduced exposure; therefore, you	5 6	conclusion of the individual authors of the studies who did the original investigations.
	result in reduced exposure; therefore, you would expect a reduced incidence of cancer in	5	conclusion of the individual authors of the studies who did the original investigations. Q. Well, it is the conclusion of
7 8	result in reduced exposure; therefore, you would expect a reduced incidence of cancer in those women.	5 6 7 8	conclusion of the individual authors of the studies who did the original investigations. Q. Well, it is the conclusion of the authors based upon their meta-analysis of
7 8 9	result in reduced exposure; therefore, you would expect a reduced incidence of cancer in those women. Q. In fact, though, that is not	5 6 7 8 9	conclusion of the individual authors of the studies who did the original investigations. Q. Well, it is the conclusion of the authors based upon their meta-analysis of eight studies; is that right?
7 8 9 10	result in reduced exposure; therefore, you would expect a reduced incidence of cancer in those women. Q. In fact, though, that is not what has been reported or at least that has	5 6 7 8 9	conclusion of the individual authors of the studies who did the original investigations. Q. Well, it is the conclusion of the authors based upon their meta-analysis of eight studies; is that right? MS. O'DELL: Object to the
7 8 9 10 11	result in reduced exposure; therefore, you would expect a reduced incidence of cancer in those women. Q. In fact, though, that is not what has been reported or at least that has not been consistently reported in the	5 6 7 8 9 10 11	conclusion of the individual authors of the studies who did the original investigations. Q. Well, it is the conclusion of the authors based upon their meta-analysis of eight studies; is that right? MS. O'DELL: Object to the form.
7 8 9 10 11 12	result in reduced exposure; therefore, you would expect a reduced incidence of cancer in those women. Q. In fact, though, that is not what has been reported or at least that has not been consistently reported in the studies; is that right?	5 6 7 8 9 10 11 12	conclusion of the individual authors of the studies who did the original investigations. Q. Well, it is the conclusion of the authors based upon their meta-analysis of eight studies; is that right? MS. O'DELL: Object to the form. A. Let me just check that.
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7 8 9 10 11 12 13 14	result in reduced exposure; therefore, you would expect a reduced incidence of cancer in those women. Q. In fact, though, that is not what has been reported or at least that has not been consistently reported in the studies; is that right? A. Well, it actually has been a positive factor in a number of the	5 6 7 8 9 10 11 12 13 14	conclusion of the individual authors of the studies who did the original investigations. Q. Well, it is the conclusion of the authors based upon their meta-analysis of eight studies; is that right? MS. O'DELL: Object to the form. A. Let me just check that. (Document review.) A. Yes.
7 8 9 10 11 12 13 14 15	result in reduced exposure; therefore, you would expect a reduced incidence of cancer in those women. Q. In fact, though, that is not what has been reported or at least that has not been consistently reported in the studies; is that right? A. Well, it actually has been a positive factor in a number of the epidemiologic studies that have looked at the	5 6 7 8 9 10 11 12 13 14 15	conclusion of the individual authors of the studies who did the original investigations. Q. Well, it is the conclusion of the authors based upon their meta-analysis of eight studies; is that right? MS. O'DELL: Object to the form. A. Let me just check that. (Document review.) A. Yes. BY MR. ZELLERS:
7 8 9 10 11 12 13 14 15	result in reduced exposure; therefore, you would expect a reduced incidence of cancer in those women. Q. In fact, though, that is not what has been reported or at least that has not been consistently reported in the studies; is that right? A. Well, it actually has been a positive factor in a number of the epidemiologic studies that have looked at the ovarian cancer incidence and have been able	5 6 7 8 9 10 11 12 13 14 15 16	conclusion of the individual authors of the studies who did the original investigations. Q. Well, it is the conclusion of the authors based upon their meta-analysis of eight studies; is that right? MS. O'DELL: Object to the form. A. Let me just check that. (Document review.) A. Yes. BY MR. ZELLERS: Q. If you look at pages 819,
7 8 9 10 11 12 13 14 15 16 17	result in reduced exposure; therefore, you would expect a reduced incidence of cancer in those women. Q. In fact, though, that is not what has been reported or at least that has not been consistently reported in the studies; is that right? A. Well, it actually has been a positive factor in a number of the epidemiologic studies that have looked at the ovarian cancer incidence and have been able to include tubal ligation as a historical	5 6 7 8 9 10 11 12 13 14 15 16 17	conclusion of the individual authors of the studies who did the original investigations. Q. Well, it is the conclusion of the authors based upon their meta-analysis of eight studies; is that right? MS. O'DELL: Object to the form. A. Let me just check that. (Document review.) A. Yes. BY MR. ZELLERS: Q. If you look at pages 819, carried over to 820, I'm reading: Our
7 8 9 10 11 12 13 14 15 16 17	result in reduced exposure; therefore, you would expect a reduced incidence of cancer in those women. Q. In fact, though, that is not what has been reported or at least that has not been consistently reported in the studies; is that right? A. Well, it actually has been a positive factor in a number of the epidemiologic studies that have looked at the ovarian cancer incidence and have been able to include tubal ligation as a historical factor in their analysis.	5 6 7 8 9 10 11 12 13 14 15 16 17	conclusion of the individual authors of the studies who did the original investigations. Q. Well, it is the conclusion of the authors based upon their meta-analysis of eight studies; is that right? MS. O'DELL: Object to the form. A. Let me just check that. (Document review.) A. Yes. BY MR. ZELLERS: Q. If you look at pages 819, carried over to 820, I'm reading: Our finding of slightly attenuated associations
7 8 9 10 11 12 13 14 15 16 17 18	result in reduced exposure; therefore, you would expect a reduced incidence of cancer in those women. Q. In fact, though, that is not what has been reported or at least that has not been consistently reported in the studies; is that right? A. Well, it actually has been a positive factor in a number of the epidemiologic studies that have looked at the ovarian cancer incidence and have been able to include tubal ligation as a historical factor in their analysis. Q. Did you look at the Terry 2013	5 6 7 8 9 10 11 12 13 14 15 16 17 18	conclusion of the individual authors of the studies who did the original investigations. Q. Well, it is the conclusion of the authors based upon their meta-analysis of eight studies; is that right? MS. O'DELL: Object to the form. A. Let me just check that. (Document review.) A. Yes. BY MR. ZELLERS: Q. If you look at pages 819, carried over to 820, I'm reading: Our finding of slightly attenuated associations following exclusion of women with powder
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7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	result in reduced exposure; therefore, you would expect a reduced incidence of cancer in those women. Q. In fact, though, that is not what has been reported or at least that has not been consistently reported in the studies; is that right? A. Well, it actually has been a positive factor in a number of the epidemiologic studies that have looked at the ovarian cancer incidence and have been able to include tubal ligation as a historical factor in their analysis. Q. Did you look at the Terry 2013 meta-analysis? A. Yes. Q. You cite that in support of	5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	conclusion of the individual authors of the studies who did the original investigations. Q. Well, it is the conclusion of the authors based upon their meta-analysis of eight studies; is that right? MS. O'DELL: Object to the form. A. Let me just check that. (Document review.) A. Yes. BY MR. ZELLERS: Q. If you look at pages 819, carried over to 820, I'm reading: Our finding of slightly attenuated associations following exclusion of women with powder exposure after tubal ligation or hysterectomy are not supportive of this hypothesis, but risk estimates in this subgroup analysis may
7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	result in reduced exposure; therefore, you would expect a reduced incidence of cancer in those women. Q. In fact, though, that is not what has been reported or at least that has not been consistently reported in the studies; is that right? A. Well, it actually has been a positive factor in a number of the epidemiologic studies that have looked at the ovarian cancer incidence and have been able to include tubal ligation as a historical factor in their analysis. Q. Did you look at the Terry 2013 meta-analysis? A. Yes.	5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	conclusion of the individual authors of the studies who did the original investigations. Q. Well, it is the conclusion of the authors based upon their meta-analysis of eight studies; is that right? MS. O'DELL: Object to the form. A. Let me just check that. (Document review.) A. Yes. BY MR. ZELLERS: Q. If you look at pages 819, carried over to 820, I'm reading: Our finding of slightly attenuated associations following exclusion of women with powder exposure after tubal ligation or hysterectomy are not supportive of this hypothesis, but

49 (Pages 190 to 193)

	AICH I. CHIP Co	,	., м.р., ғи.р.
	Page 194		Page 196
1	size.	1	THE WITNESS: Thank you.
2	Is that right?	2	MS. O'DELL: Thank you.
3	A. Yes.	3	BY MR. ZELLERS:
4	Q. Essentially, looking at these	4	Q. This is also a study,
5	eight studies in this meta-analysis, Terry	5	Exhibit 20, Cramer 2016, that you cite as
6	did not find that exposure to genital powder	6	supportive of your opinions in this case,
7	applications that occurred before tubal	7	correct?
8	ligation or hysterectomy made any substantive	8	A. Correct.
9	difference in the results; is that right?	9	Q. Cramer actually looked at
10	A. Yes, but the point is that the	10	whether or not there was any greater
11	authors didn't find that it did not make a	11	association of talc use and ovarian cancer
12	difference either. They they ended up	12	and whether or not women who had a tubal
13	with a study with reduced numbers that they	13	ligation or hysterectomy had a reduced
14	couldn't make determinations about.	14	incidence of the disease; is that correct?
15	Q. If, though, the migration	15	A. Yes.
16	theory is correct, you would expect that	16	Q. Turn to page 337, and then it
17	there would be a reduction in the incidence	17	carries over to 339. They're talking
18	of ovarian cancer for women who have had a	18	they, being the authors of their results,
19	tubal ligation or hysterectomy; is that	19	and I'm reading just at the very bottom of
20	right?	20	337, carried over to 339: By test for
21	MS. O'DELL: Object to the	21	interaction, column 3, the association was
22	form.	22	significantly greater for women who were
23	A. Yes, that is correct.	23	African-American, had no personal history of
24	A. Tes, that is correct.	24	breast cancer, had a tubal ligation or
24	<i>///</i>	24	breast cancer, nad a tubar rigation or
	Page 195		Page 197
1	BY MR. ZELLERS:	1	hysterectomy.
2	Q. And that was not found in the	2	Is that right?
3	Terry meta-analysis that you cite; is that	3	MS. O'DELL: Object to the
4	right?	4	form.
5	MS. O'DELL: Object to the	5	A. Beginning on page 337?
6	form.	6	BY MR. ZELLERS:
7	A. That is correct, but it was	7	Q. Yes.
8	found in the baseline studies that were, in	8	A. I'm sorry, if you could
9	part, included in this meta-analysis.	9	Q. Sure. At the very end of 337.
10	BY MR. ZELLERS:	10	A. Okay.
11	Q. Are you you also cite the	11	Q. So they're looking at
12	Cramer study, 2016; is that right?	12	A. Oh, by tests for interaction.
13	A. Yes.	13	Q. Yes.
14	Q. I've got a few questions for	14	A. Yeah.
15	you on the Cramer study, but let me just ask,	15	Q. So if your migration theory is
16	since we're at this part right now.	16	correct, you would expect there to be a lower
17	Do you have the Cramer study?	17	incidence of ovarian cancer in women who have
18	I'll hand it to you.	18	had a tubal ligation or hysterectomy,
19	A. If you have a copy, I'd	19	correct?
20	appreciate it.	20	MS. O'DELL: Object to the
21	MR. ZELLERS: Sure. We'll mark	21	form.
22	the Cramer study as Exhibit 20.	22	A. That is correct.
23	(Carson Deposition Exhibit 20	23	BY MR. ZELLERS:
	(Carson Deposition Lamon 20	_ <u>_</u>	DI MIN, AELLEND,
24	marked.)	24	Q. All right. Cramer finds by

50 (Pages 194 to 197)

	Alch I. Chip Co		, м.р., ғп.р.
	Page 198		Page 200
1	test for interaction the association was	1	to talcum powder?
2	significantly greater for women who and	2	MS. O'DELL: Object to the
3	then I'm skipping African-American, but I'm	3	form.
4	coming down to have a tubal ligation or	4	A. It doesn't it doesn't
5	hysterectomy.	5	eliminate exposure, but it does remove
6	Is that correct?	6	residual exposure, as does sweating, other
7	A. Yes.	7	body secretions and so forth.
8	Q. All right. If talcum powder	8	BY MR. ZELLERS:
9	migrates from the perineal region to the	9	Q. Are you aware of any studies
10	ovaries, shouldn't exposure to exposure to	10	that show inflammation or oxidative stress as
11	talc be far greater in concentration in the	11	a result of genital talc use in the rectal,
12	rectal, vulvar, vaginal, cervical and uterine	12	vulvar, vaginal, cervical and uterine
13	tissues which are closer to the area of	13	tissues?
14	initial exposure?	14	A. No, I'm not.
15	MS. O'DELL: Objection to form.	15	Q. Under your theory or belief
16	A. Well, the acute exposure would	16	that talcum powder travels from the perineal
17	be greater.	17	region to the ovaries through the woman's
18	BY MR. ZELLERS:	18	reproductive tract, talcum powder must travel
19	Q. You would expect because the	19	past the labia, through the vagina, through
20	acute exposure is greater, that there should	20	the cervix, and then to the uterus; is that
21	be inflammation caused in these organs and	21	right?
22	areas, correct?	22	A. That's correct.
23	A. No. The inflammation and	23	Q. And then the powder travels
24		24	through the uterus and into the fallopian
24	oxidative stress is an ongoing process that	24	unough the dierus and into the fanopian
	Page 199		Page 201
1	has to develop over time, and it occurs on a	1	tubes to reach the ovaries; is that right?
2	chronic basis in areas where foreign bodies	2	A. Yes.
3	locate and reside. And talc and talcum	3	Q. On what studies are you relying
4	powder are examples of foreign bodies that	4	to say that talcum powder affects the body
5	have the right characteristics to cause	5	differently when it's applied to the perineal
6	chemotaxis in reactive oxygen species and	6	region and travels to the cervix compared to
7	oxidative status.	7	when it is applied directly to the cervix?
8	Q. Well, in fact, there would be	8	A. I don't think
9	chronic exposure, so if we're dealing with,	9	MS. O'DELL: Object to the
10	as you described in the very beginning, which	10	form.
11	you were asked, to look at the habitual use	11	A there is much of a
12	of talcum powder, that would create exposure	12	difference.
13	on a chronic basis to the rectal area and	13	BY MR. ZELLERS:
14	tissues, vulvar, vaginal, cervical and	14	Q. You would expect there to be a
15	uterine tissues; is that right?	15	comparable similar result whether talcum
16	MS. O'DELL: Object to the	16	powder is applied directly to the cervix
17	form.	17	through the use of dusting of a diaphragm as
18	A. I suspect if one doesn't bathe,	18	there is to the use of talcum powder in the
19	that would be more of an issue, but most	19	genital areas; is that right?
20	people bathe regularly as well.	20	A. That is correct. I think the
21	BY MR. ZELLERS:	21	two differ probably in terms of quantity very
22	Q. And bathing regularly	22	significantly. But other than that, they
23	eliminates any exposure in the rectal,	23	would be the same.
23 24	vulvar, vaginal, cervical and uterine tissues	24	Q. When applied to the perineal
47	varvar, vaginar, cervicar and uterine ussues	44	Q. when applied to the perillear

51 (Pages 198 to 201)

	Page 202		Page 204
1	region, talcum powder would also be in close	1	about to reconsider that?
2	contact with a woman's urethra; is that	2	A. Because the chatter is that
3	right?	3	this is something that's on their radar
4	A. Yes.	4	screen currently.
5	Q. Substances, and in your view,	5	Q. What chatter are you aware of?
6	talcum powder, are capable of traveling up	6	And what is chatter?
7	the urethra; is that right?	7	A. It's discussion among within
8	MS. O'DELL: Object to the	8	the scientific and healthcare community of
9	form.	9	things that are on the drawing board for
10	A. The urethra has a sphincter	10	IARC.
11	which prevents transport beyond that point.	11	Q. Do you know whether or not
12	BY MR. ZELLERS:	12	IARC well, strike that.
13		13	
	Q. Women get urinary tract		IARC has not changed its
14	infections when bacteria travels up the	14	position that the migration theory and
15	urethra; is that right?	15	evidence for the migration theory is weak; is
16	A. That's correct.	16	that right?
17	Q. Studies, though, do not show an	17	MS. O'DELL: Object to the
18	increase in bladder cancer with talcum powder	18	form.
19	use; is that right?	19	A. They have not changed their
20	A. I don't believe that talcum	20	position that was published in the 2010
21	powder transports in any appreciable amount	21	monograph.
22	up the urethra into the bladder.	22	BY MR. ZELLERS:
23	Q. Studies do not show an increase	23	Q. All right. You have heard
24	in rectal cancer with talcum powder use, do	24	chatter that they may look at it again; is
	Page 203		Page 205
1	they?	1	that right?
2	·		
	A. No.	2	A. Yes.
3	A. No. Q. Are you aware that that IARC	2 3	
3 4			A. Yes.Q. Other than this chatter, you're
	Q. Are you aware that that IARC	3	A. Yes. Q. Other than this chatter, you're unaware of any other well, strike that.
4	Q. Are you aware that that IARC and you're familiar with IARC, right? A. Yes.	3 4	A. Yes. Q. Other than this chatter, you're unaware of any other well, strike that. You're unaware of any change in
4 5 6	Q. Are you aware that that IARC and you're familiar with IARC, right? A. Yes. Q. Are you aware that IARC rejects	3 4 5 6	A. Yes. Q. Other than this chatter, you're unaware of any other well, strike that. You're unaware of any change in IARC's position with respect to migration,
4 5	 Q. Are you aware that that IARC and you're familiar with IARC, right? A. Yes. Q. Are you aware that IARC rejects this migration theory and calls the evidence 	3 4 5 6 7	A. Yes. Q. Other than this chatter, you're unaware of any other well, strike that. You're unaware of any change in IARC's position with respect to migration, correct?
4 5 6 7 8	Q. Are you aware that that IARC and you're familiar with IARC, right? A. Yes. Q. Are you aware that IARC rejects this migration theory and calls the evidence weak?	3 4 5 6 7 8	A. Yes. Q. Other than this chatter, you're unaware of any other well, strike that. You're unaware of any change in IARC's position with respect to migration, correct? A. Well, an example of what I'm
4 5 6 7 8 9	Q. Are you aware that that IARC and you're familiar with IARC, right? A. Yes. Q. Are you aware that IARC rejects this migration theory and calls the evidence weak? MS. O'DELL: Object to the	3 4 5 6 7 8 9	A. Yes. Q. Other than this chatter, you're unaware of any other well, strike that. You're unaware of any change in IARC's position with respect to migration, correct? A. Well, an example of what I'm talking about is the Health Canada report,
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4 5 6 7 8 9 10 11 12 13 14 15	Q. Are you aware that that IARC and you're familiar with IARC, right? A. Yes. Q. Are you aware that IARC rejects this migration theory and calls the evidence weak? MS. O'DELL: Object to the form. A. The IARC has made that statement in their I think the 2006 review that resulted in their recent monograph, but I think they're about to reconsider that. BY MR. ZELLERS: Q. Well, they also have stated	3 4 5 6 7 8 9 10 11 12 13 14 15 16	A. Yes. Q. Other than this chatter, you're unaware of any other well, strike that. You're unaware of any change in IARC's position with respect to migration, correct? A. Well, an example of what I'm talking about is the Health Canada report, which has contradicted what is found in the IARC monograph and is more current and considers information that will probably go into the next IARC review. MR. ZELLERS: Move to strike as nonresponsive. BY MR. ZELLERS:
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4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Q. Are you aware that that IARC and you're familiar with IARC, right? A. Yes. Q. Are you aware that IARC rejects this migration theory and calls the evidence weak? MS. O'DELL: Object to the form. A. The IARC has made that statement in their I think the 2006 review that resulted in their recent monograph, but I think they're about to reconsider that. BY MR. ZELLERS: Q. Well, they also have stated that in 2010; is that right? A. Well, that's the MS. O'DELL: Object to the form. A. That's the monograph from the	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	A. Yes. Q. Other than this chatter, you're unaware of any other well, strike that. You're unaware of any change in IARC's position with respect to migration, correct? A. Well, an example of what I'm talking about is the Health Canada report, which has contradicted what is found in the IARC monograph and is more current and considers information that will probably go into the next IARC review. MR. ZELLERS: Move to strike as nonresponsive. BY MR. ZELLERS: Q. Does IARC review and rely on draft assessments in formulating their positions? A. IARC relies on primary studies. Q. Not draft assessments, correct?
4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q. Are you aware that that IARC and you're familiar with IARC, right? A. Yes. Q. Are you aware that IARC rejects this migration theory and calls the evidence weak? MS. O'DELL: Object to the form. A. The IARC has made that statement in their I think the 2006 review that resulted in their recent monograph, but I think they're about to reconsider that. BY MR. ZELLERS: Q. Well, they also have stated that in 2010; is that right? A. Well, that's the MS. O'DELL: Object to the form. A. That's the monograph from the 2006 review.	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. Yes. Q. Other than this chatter, you're unaware of any other well, strike that. You're unaware of any change in IARC's position with respect to migration, correct? A. Well, an example of what I'm talking about is the Health Canada report, which has contradicted what is found in the IARC monograph and is more current and considers information that will probably go into the next IARC review. MR. ZELLERS: Move to strike as nonresponsive. BY MR. ZELLERS: Q. Does IARC review and rely on draft assessments in formulating their positions? A. IARC relies on primary studies. Q. Not draft assessments, correct? A. Well, the draft assessment that
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	Alch I. Chip Co		
	Page 206		Page 208
1	primary studies, the same ones that will be	1	is that right?
2	considered by IARC.	2	A. That is correct.
3	Q. All right. As of today, IARC's	3	Q. You are not one of those
4	published position is that evidence of a	4	physicians, correct?
5	migration theory of talcum powder migrating	5	A. I don't claim to be a
6	to the ovaries is weak, correct?	6	specialist in gynecology.
7	A. Yes.	7	Q. Your third opinion is that the
8	Q. Have you conducted any tests or	8	ovaries lack an intrinsic elimination system;
9	experiments with respect to your theory or	9	is that right?
10	position that talc migrates to the ovaries	10	A. That's correct.
11	through the reproductive tract?	11	Q. Is "intrinsic elimination
12	A. No, I haven't.	12	system" a recognized term of art that's used
13	Q. How much talc actually reaches	13	by gynecologists?
14	the ovaries in your opinion?	14	A. I don't think so. It was just
15	A. I can't answer that question	15	the term I used to describe the situation.
16	because the dose has not been quantified.	16	Q. Is "intrinsic elimination
17	Q. Does it only reach the ovaries	17	-
18	•	18	system" a term of art used by oncologists?
	during certain times?	1	A. The same answer.
19	A. I don't believe so. I think	19	Q. Have you seen published studies
20	there are many circumstances whereby that	20	that use that term?
21	migration pathway is functional, and in my	21	A. I don't know. I suspect I
22	belief, the pathway from the perineum to the	22	could have. It's apparently a small number
23	cervix is pretty much an open channel, and	23	of ways to describe that in a few words.
24	then it continues to be open pretty much all	24	Q. You do not cite to any studies
	Page 207		Page 209
1	the way into the pelvic cavity.	1	in the body of your report to support your
2	Q. You are not a specialist in	2	theory that the ovaries do not have an
3	women's health issues, correct?	3	intrinsic elimination system, correct?
4	MS. O'DELL: Object to the	4	A. That's correct.
5	form.	5	Q. You have not conducted any
6	A. Well, I'm a doctor. I've	6	tests to show that exposure to the ovaries to
7	examined a lot of women.	7	particulate matter, if any, is longer than
8	BY MR. ZELLERS:	8	exposure to other parts of the female
9	Q. Are you	9	anatomy; is that right?
10	MS. O'DELL: Excuse me. Are	10	MS. O'DELL: Object to the
11	you finished, sir?	11	form.
12	THE WITNESS: Yes, I'm	12	A. I have not conducted any such
13	finished.	13	tests.
14	MS. O'DELL: Okay.	14	BY MR. ZELLERS:
15	BY MR. ZELLERS:	15	Q. Is the cervix more or less
16	Q. Are you an expert in the	16	
17	women's reproductive tract?	17	sensitive to the impact of foreign particles than the ovaries?
	*	l .	
18	A. I've taken it apart and put it	18	MS. O'DELL: Object to the
	back together again in medical school, and in	19	form.
19	other settings I've done OB/GYN rotations.	20	A. I think that the important
20			
20 21	I've participated in pelvic surgeries. I	21	point is the residence time that exists, and
20 21 22	I've participated in pelvic surgeries. I understand the anatomy.	22	the cervix is not presented with things for
20 21	I've participated in pelvic surgeries. I		

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	Page 210		Page 212
1	sensitive.	1	A. Yes.
2	BY MR. ZELLERS:	2	MS. O'DELL: Object to the
3	Q. All right. Your fourth	3	form.
4	theory or strike that.	4	BY MR. ZELLERS:
5	Your fourth opinion is that the	5	Q. Are you familiar with the term
6	epidemiological studies show a positive	6	"person-years" as it relates to
7	relationship between regular perineal	7	epidemiological study?
8	application of talcum powder and ovarian	8	A. Yes, I am.
9	cancer; is that right?	9	Q. What is strike that.
10	A. That's correct.	10	How are person-years
11	Q. The studies that you reference	11	calculated?
12	in this opinion are referred to on pages 6	12	A. They are calculated by in
13	and 7 of your report; is that right?	13	relation to an exposure or to an existing
14	MS. O'DELL: Object to the	14	treatment, they're calculated by multiplying
15	form.	15	the duration of the treatment or exposure in
16	A. Most of them, yes.	16	years by the number of people being studied.
17	BY MR. ZELLERS:	17	And that the result is person-years.
18	Q. You conclude that when	18	Q. Can you explain the difference
19	confounding and bias are exhaustively	19	between high-grade serous and low-grade
20	considered and do you believe you've done	20	serous cancer?
21	that here?	21	A. High-grade serous cancer has
22	A. I am restating what authors of	22	a is less differentiated and has a greater
23	the primary studies have done. I'm	23	propensity for metastasis and invasion.
24	evaluating the consistency of the evidence,	24	Q. Are you aware that the
	Page 211		Page 213
			1490 213
1	not the basic evidence itself	1	
1 2	not the basic evidence itself. O. The apparent cause and effect	1 2	epidemiological literature shows that these
1 2 3	Q. The apparent cause and effect	1 2 3	epidemiological literature shows that these are very different cancers?
2		2	epidemiological literature shows that these are very different cancers? A. They behave quite differently,
2	Q. The apparent cause and effect relationship between perineal talcum powder	2 3 4	epidemiological literature shows that these are very different cancers? A. They behave quite differently, yes.
2 3 4	Q. The apparent cause and effect relationship between perineal talcum powder use and ovarian cancer amounts to about a 30% increased risk of ovarian cancer in talcum	2 3	epidemiological literature shows that these are very different cancers? A. They behave quite differently,
2 3 4 5	Q. The apparent cause and effect relationship between perineal talcum powder use and ovarian cancer amounts to about a 30%	2 3 4 5	epidemiological literature shows that these are very different cancers? A. They behave quite differently, yes. Q. Do you know what publication
2 3 4 5 6	Q. The apparent cause and effect relationship between perineal talcum powder use and ovarian cancer amounts to about a 30% increased risk of ovarian cancer in talcum powder users.	2 3 4 5 6	epidemiological literature shows that these are very different cancers? A. They behave quite differently, yes. Q. Do you know what publication bias is?
2 3 4 5 6 7	Q. The apparent cause and effect relationship between perineal talcum powder use and ovarian cancer amounts to about a 30% increased risk of ovarian cancer in talcum powder users. Is that your opinion in this	2 3 4 5 6 7	epidemiological literature shows that these are very different cancers? A. They behave quite differently, yes. Q. Do you know what publication bias is? A. Yes.
2 3 4 5 6 7 8 9	Q. The apparent cause and effect relationship between perineal talcum powder use and ovarian cancer amounts to about a 30% increased risk of ovarian cancer in talcum powder users. Is that your opinion in this case? A. It is. Q. And that is your opinion from	2 3 4 5 6 7 8 9	epidemiological literature shows that these are very different cancers? A. They behave quite differently, yes. Q. Do you know what publication bias is? A. Yes. Q. What is publication bias? A. Publication bias is the tendency to to spin a certain argument
2 3 4 5 6 7 8 9 10	Q. The apparent cause and effect relationship between perineal talcum powder use and ovarian cancer amounts to about a 30% increased risk of ovarian cancer in talcum powder users. Is that your opinion in this case? A. It is. Q. And that is your opinion from reviewing the epidemiologic studies that you	2 3 4 5 6 7 8 9 10	epidemiological literature shows that these are very different cancers? A. They behave quite differently, yes. Q. Do you know what publication bias is? A. Yes. Q. What is publication bias? A. Publication bias is the tendency to to spin a certain argument in in order to influence acceptance of
2 3 4 5 6 7 8 9 10 11	Q. The apparent cause and effect relationship between perineal talcum powder use and ovarian cancer amounts to about a 30% increased risk of ovarian cancer in talcum powder users. Is that your opinion in this case? A. It is. Q. And that is your opinion from reviewing the epidemiologic studies that you cite in your report?	2 3 4 5 6 7 8 9 10 11	epidemiological literature shows that these are very different cancers? A. They behave quite differently, yes. Q. Do you know what publication bias is? A. Yes. Q. What is publication bias? A. Publication bias is the tendency to to spin a certain argument in in order to influence acceptance of publications.
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2 3 4 5 6 7 8 9 10 11 12 13 14	Q. The apparent cause and effect relationship between perineal talcum powder use and ovarian cancer amounts to about a 30% increased risk of ovarian cancer in talcum powder users. Is that your opinion in this case? A. It is. Q. And that is your opinion from reviewing the epidemiologic studies that you cite in your report? A. Yes. Q. When epidemiologists refer to	2 3 4 5 6 7 8 9 10 11 12 13	epidemiological literature shows that these are very different cancers? A. They behave quite differently, yes. Q. Do you know what publication bias is? A. Yes. Q. What is publication bias? A. Publication bias is the tendency to to spin a certain argument in in order to influence acceptance of publications. Q. Is that a recognized issue in the field of epidemiology, at least as you've
2 3 4 5 6 7 8 9 10 11 12 13 14 15	Q. The apparent cause and effect relationship between perineal talcum powder use and ovarian cancer amounts to about a 30% increased risk of ovarian cancer in talcum powder users. Is that your opinion in this case? A. It is. Q. And that is your opinion from reviewing the epidemiologic studies that you cite in your report? A. Yes. Q. When epidemiologists refer to the statistical power of a study, what are	2 3 4 5 6 7 8 9 10 11 12 13 14 15	epidemiological literature shows that these are very different cancers? A. They behave quite differently, yes. Q. Do you know what publication bias is? A. Yes. Q. What is publication bias? A. Publication bias is the tendency to to spin a certain argument in in order to influence acceptance of publications. Q. Is that a recognized issue in the field of epidemiology, at least as you've observed?
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	Q. The apparent cause and effect relationship between perineal talcum powder use and ovarian cancer amounts to about a 30% increased risk of ovarian cancer in talcum powder users. Is that your opinion in this case? A. It is. Q. And that is your opinion from reviewing the epidemiologic studies that you cite in your report? A. Yes. Q. When epidemiologists refer to the statistical power of a study, what are they referring to?	2 3 4 5 6 7 8 9 10 11 12 13 14 15	epidemiological literature shows that these are very different cancers? A. They behave quite differently, yes. Q. Do you know what publication bias is? A. Yes. Q. What is publication bias? A. Publication bias is the tendency to to spin a certain argument in in order to influence acceptance of publications. Q. Is that a recognized issue in the field of epidemiology, at least as you've observed? A. It's a it's not necessarily
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	Q. The apparent cause and effect relationship between perineal talcum powder use and ovarian cancer amounts to about a 30% increased risk of ovarian cancer in talcum powder users. Is that your opinion in this case? A. It is. Q. And that is your opinion from reviewing the epidemiologic studies that you cite in your report? A. Yes. Q. When epidemiologists refer to the statistical power of a study, what are they referring to? A. Statistical power refers to the	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	epidemiological literature shows that these are very different cancers? A. They behave quite differently, yes. Q. Do you know what publication bias is? A. Yes. Q. What is publication bias? A. Publication bias is the tendency to to spin a certain argument in in order to influence acceptance of publications. Q. Is that a recognized issue in the field of epidemiology, at least as you've observed? A. It's a it's not necessarily recognized in the field of epidemiology. It
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	Q. The apparent cause and effect relationship between perineal talcum powder use and ovarian cancer amounts to about a 30% increased risk of ovarian cancer in talcum powder users. Is that your opinion in this case? A. It is. Q. And that is your opinion from reviewing the epidemiologic studies that you cite in your report? A. Yes. Q. When epidemiologists refer to the statistical power of a study, what are they referring to? A. Statistical power refers to the ability of a study design, if carried out, to detect a signal in the data of a particular	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	epidemiological literature shows that these are very different cancers? A. They behave quite differently, yes. Q. Do you know what publication bias is? A. Yes. Q. What is publication bias? A. Publication bias is the tendency to to spin a certain argument in in order to influence acceptance of publications. Q. Is that a recognized issue in the field of epidemiology, at least as you've observed? A. It's a it's not necessarily recognized in the field of epidemiology. It exists in all scientific endeavors. Q. Is it something that you and
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	Q. The apparent cause and effect relationship between perineal talcum powder use and ovarian cancer amounts to about a 30% increased risk of ovarian cancer in talcum powder users. Is that your opinion in this case? A. It is. Q. And that is your opinion from reviewing the epidemiologic studies that you cite in your report? A. Yes. Q. When epidemiologists refer to the statistical power of a study, what are they referring to? A. Statistical power refers to the ability of a study design, if carried out, to detect a signal in the data of a particular magnitude.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	epidemiological literature shows that these are very different cancers? A. They behave quite differently, yes. Q. Do you know what publication bias is? A. Yes. Q. What is publication bias? A. Publication bias is the tendency to to spin a certain argument in in order to influence acceptance of publications. Q. Is that a recognized issue in the field of epidemiology, at least as you've observed? A. It's a it's not necessarily recognized in the field of epidemiology. It exists in all scientific endeavors. Q. Is it something that you and other physicians and experts and scientists
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Q. The apparent cause and effect relationship between perineal talcum powder use and ovarian cancer amounts to about a 30% increased risk of ovarian cancer in talcum powder users. Is that your opinion in this case? A. It is. Q. And that is your opinion from reviewing the epidemiologic studies that you cite in your report? A. Yes. Q. When epidemiologists refer to the statistical power of a study, what are they referring to? A. Statistical power refers to the ability of a study design, if carried out, to detect a signal in the data of a particular magnitude. Q. In plain English, statistical	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	epidemiological literature shows that these are very different cancers? A. They behave quite differently, yes. Q. Do you know what publication bias is? A. Yes. Q. What is publication bias? A. Publication bias is the tendency to to spin a certain argument in in order to influence acceptance of publications. Q. Is that a recognized issue in the field of epidemiology, at least as you've observed? A. It's a it's not necessarily recognized in the field of epidemiology. It exists in all scientific endeavors. Q. Is it something that you and other physicians and experts and scientists need to be aware of?
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q. The apparent cause and effect relationship between perineal talcum powder use and ovarian cancer amounts to about a 30% increased risk of ovarian cancer in talcum powder users. Is that your opinion in this case? A. It is. Q. And that is your opinion from reviewing the epidemiologic studies that you cite in your report? A. Yes. Q. When epidemiologists refer to the statistical power of a study, what are they referring to? A. Statistical power refers to the ability of a study design, if carried out, to detect a signal in the data of a particular magnitude. Q. In plain English, statistical power is the likelihood that a study will	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	epidemiological literature shows that these are very different cancers? A. They behave quite differently, yes. Q. Do you know what publication bias is? A. Yes. Q. What is publication bias? A. Publication bias is the tendency to to spin a certain argument in in order to influence acceptance of publications. Q. Is that a recognized issue in the field of epidemiology, at least as you've observed? A. It's a it's not necessarily recognized in the field of epidemiology. It exists in all scientific endeavors. Q. Is it something that you and other physicians and experts and scientists need to be aware of? A. Yes. I think we're all exposed
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Q. The apparent cause and effect relationship between perineal talcum powder use and ovarian cancer amounts to about a 30% increased risk of ovarian cancer in talcum powder users. Is that your opinion in this case? A. It is. Q. And that is your opinion from reviewing the epidemiologic studies that you cite in your report? A. Yes. Q. When epidemiologists refer to the statistical power of a study, what are they referring to? A. Statistical power refers to the ability of a study design, if carried out, to detect a signal in the data of a particular magnitude. Q. In plain English, statistical	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	epidemiological literature shows that these are very different cancers? A. They behave quite differently, yes. Q. Do you know what publication bias is? A. Yes. Q. What is publication bias? A. Publication bias is the tendency to to spin a certain argument in in order to influence acceptance of publications. Q. Is that a recognized issue in the field of epidemiology, at least as you've observed? A. It's a it's not necessarily recognized in the field of epidemiology. It exists in all scientific endeavors. Q. Is it something that you and other physicians and experts and scientists need to be aware of?

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Q. When I asked you early on what your methodology was, you looked at the published literature, you looked at some websites I think that you told us about earlier, and then you performed a risk assessment and considered whether perineal use of talc products poses a safety risk to consumers; is that right? MS. O'DELL: Object to the form. A. Well, that's a gross oversimplification of the risk assessment process that I performed. The review of the literature, which was based on the question that I was asked to address, was a fairly exhaustive one which incorporated a search for every pertinent publication that was available and included multiple languages. It then was proceeded into a distillation of the facts that were that were claimed based on those individual studies and investigations, and a comparison of those, one with another, eventually	been published as well. And I felt that was sufficient to be able to produce this report that addressed the question I was asked. Q. As you told us earlier, you have never published a meta-analysis on any topic; is that right? A. That's correct. Q. You cite to some of the available studies on talcum powder use in ovarian cancer, but not to all of the studies, correct? MS. O'DELL: Object to the form. A. That's true. BY MR. ZELLERS: Q. What was your reasoning for focusing on certain studies and excluding other studies? A. The studies that I referenced were those that had specific aspects that directly influenced my report or my conclusions or that I felt were illustrative of comments I was making in the report, and that's why they were referenced.
considering them all as a whole to arrive at conclusions that addressed the question. BY MR. ZELLERS: Q. That was your methodology; is that right? A. That is the methodology, yes. Q. Did you consider the Bradford Hill criteria or factors in reaching your conclusions and opinions in this matter? A. That's part of the methodology which is outlined in my report. Q. In analyzing the Bradford Hill criteria, did you conduct a meta-analysis of the available data to reach a conclusion about the relative risk? A. No, I did not. Q. Why didn't you conduct a meta-analysis for this case? A. I did not have the time to do a meta-analysis in this case, first of all. Secondly, there have been a number of other meta-analyses performed, and I had those results available to me in addition to various reviews of the literature that have	All of the studies may not have risen to that the level of requiring being referenced, but pretty much all the studies are included in the literature that I reviewed. Q. You cite in the report the studies that were favorable or supportive of your opinions, correct? A. Well, I cited a number of studies, not all of which were favorable to my overall opinions, at least not on the surface. Q. Did you cite all of the studies that you believe in one way or another support your opinions in this case? A. I don't think so. Q. You believe there are additional studies that support your opinions that you did not cite? A. They're in the literature list. Q. Did you cite the opinions that refuted strike that. Did you cite the studies that refuted your opinions in this matter?

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	Page 218		Page 220
1	A. I cited some studies that had	1	more detail to be able to answer that
1 2 3 4 5	opinions that or that had conclusions that	2	specifically.
ا	did not necessarily agree with mine, but I	3	Q. Well, essentially, based upon
4	don't think they refuted my conclusions.	4	its analysis as of 2014, the FDA concluded
5	Q. Do you believe the standard for	5	that causation had not been established as
6	proving causation in the scientific	6	between genital talcum powder use and ovarian
7	literature is the same one that applies in	7	cancer or an increased risk of ovarian
8	**	8	cancer, correct?
9	this litigation?	9	·
10	MS. O'DELL: Object to the	10	A. Well, it said that an updated
	form.	l	review failed to identify any new compelling
11	A. I don't know that.	11	literature data or new scientific evidence.
12	BY MR. ZELLERS:	12	I don't think they indicate here that they
13	Q. A document you brought here	13	actually did a standard review of that
14	today was an FDA letter?	14	literature.
15	A. Yeah, I think you marked it.	15	Q. Well, take a look, if you will,
16	Q. I did mark it. Why don't you	16	at page 4. The FDA sets forth its
17	see if you could find it so I can ask you a	17	epidemiology and etiology findings; is that
18	couple of questions about it.	18	right?
19	A. There it is. That one?	19	A. Yes.
20	Q. Yes. Exhibit 10 is an FDA	20	Q. The FDA has a number of very
21	letter dated April 1st of 2014 to a	21	capable physicians, scientists,
22	Dr. Epstein; is that right?	22	toxicologists, pharmacologists and medical
23	A. Yes.	23	professionals; is that right?
24	Q. That is a document that you	24	MS. O'DELL: Object to the
	•		
	Page 219		Page 221
1	_	1	_
	reviewed and considered as part of your	1 2	form.
2	reviewed and considered as part of your analysis of this case; is that right?	2	form. A. I don't know if they're still
2 3	reviewed and considered as part of your analysis of this case; is that right? A. Yes.	2 3	form. A. I don't know if they're still working, but they have good people on staff.
2 3 4	reviewed and considered as part of your analysis of this case; is that right? A. Yes. Q. Do you believe that that	2 3 4	form. A. I don't know if they're still working, but they have good people on staff. BY MR. ZELLERS:
2 3 4 5	reviewed and considered as part of your analysis of this case; is that right? A. Yes. Q. Do you believe that that exhibit, Exhibit 10, is supportive of your	2 3 4 5	form. A. I don't know if they're still working, but they have good people on staff. BY MR. ZELLERS: Q. And just so, a year or two or
2 3 4 5 6	reviewed and considered as part of your analysis of this case; is that right? A. Yes. Q. Do you believe that that exhibit, Exhibit 10, is supportive of your opinions in this matter?	2 3 4 5 6	form. A. I don't know if they're still working, but they have good people on staff. BY MR. ZELLERS: Q. And just so, a year or two or three, if this transcript is ever reviewed,
2 3 4 5 6 7	reviewed and considered as part of your analysis of this case; is that right? A. Yes. Q. Do you believe that that exhibit, Exhibit 10, is supportive of your opinions in this matter? A. I don't think it's very	2 3 4 5 6 7	form. A. I don't know if they're still working, but they have good people on staff. BY MR. ZELLERS: Q. And just so, a year or two or three, if this transcript is ever reviewed, we are in the midst of a shutdown of at least
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	reviewed and considered as part of your analysis of this case; is that right? A. Yes. Q. Do you believe that that exhibit, Exhibit 10, is supportive of your opinions in this matter? A. I don't think it's very supportive. It's it's in response to a proposal from a citizens voluntary agency to provide more stringent labeling on talcum powder products, and the agency rejected the that petition. Q. The FDA is the regulatory body in the United States that oversees food, drug and cosmetics; is that right? MS. O'DELL: Object to the form. A. Yes. BY MR. ZELLERS: Q. This letter strike that. In this letter the FDA goes through and analyzes some of the Bradford	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	form. A. I don't know if they're still working, but they have good people on staff. BY MR. ZELLERS: Q. And just so, a year or two or three, if this transcript is ever reviewed, we are in the midst of a shutdown of at least portions of the government; is that right? A. That's correct. Q. And that is what your comment was directed to, correct? A. That is correct. Q. On page 4 the FDA states: After consideration of the scientific literature submitted in support of both citizens' petitions, FDA found. And then, number 2, that several of the studies acknowledge biases in the study design and no single study has considered all the factors that potentially contribute to ovarian cancer, including selection bias and/or uncontrolled
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	reviewed and considered as part of your analysis of this case; is that right? A. Yes. Q. Do you believe that that exhibit, Exhibit 10, is supportive of your opinions in this matter? A. I don't think it's very supportive. It's it's in response to a proposal from a citizens voluntary agency to provide more stringent labeling on talcum powder products, and the agency rejected the that petition. Q. The FDA is the regulatory body in the United States that oversees food, drug and cosmetics; is that right? MS. O'DELL: Object to the form. A. Yes. BY MR. ZELLERS: Q. This letter strike that. In this letter the FDA goes through and analyzes some of the Bradford	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	form. A. I don't know if they're still working, but they have good people on staff. BY MR. ZELLERS: Q. And just so, a year or two or three, if this transcript is ever reviewed, we are in the midst of a shutdown of at least portions of the government; is that right? A. That's correct. Q. And that is what your comment was directed to, correct? A. That is correct. Q. On page 4 the FDA states: After consideration of the scientific literature submitted in support of both citizens' petitions, FDA found. And then, number 2, that several of the studies acknowledge biases in the study design and no single study has considered all the factors that potentially contribute to ovarian cancer, including selection bias and/or uncontrolled

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		1	
	Page 222		Page 224
1	cancer risk.	1	form.
2	Did I read that correctly?	2	A. That is correct.
3	A. You did read it correctly.	3	BY MR. ZELLERS:
4	Q. Does that appear to be at least	4	Q. You are a paid expert for the
5	one of the conclusions of the FDA after	5	plaintiffs in this litigation; is that right?
6	considering the scientific literature as of	6	A. That is correct.
7	early 2014?	7	Q. To your knowledge, the FDA is
8	MS. O'DELL: Object to the	8	not paid well, let me withdraw that.
9	form.	9	A. I wouldn't go out on a limb
10	A. Yes, that is listed as an FDI	10	there.
11	finding FDA finding.	11	Q. Number 4, Conclusion 4, a
12	BY MR. ZELLERS:	12	cogent biological mechanism by which tale
13	Q. The FDA noted that a	13	might lead to ovarian cancer is lacking.
14	dose-response strike that.	14	Exposure to talc does not account for all
15	The FDA noted that	15	cases of ovarian cancer and there was no
16	dose-response evidence is lacking; is that	16	scientific consensus on the proportion of
17	right?	17	ovarian cancer cases that may be caused by
18		18	
19	A. A dose-response	19	talc exposure. Was that a conclusion of the
20	Q. Two things. The FDA notes that	20	
21	there's a lack of consistency in the study	21	FDA based upon its review of the
22	results, correct?	22	epidemiologic literature?
	MS. O'DELL: Where are you		MS. O'DELL: Object to the
23	reading? I'm sorry.	23	form.
24	MR. ZELLERS: I'm looking at	24	A. Yes, it was, and it's one that
	Page 223		Page 225
1	Conclusion 3.	1	I also disagree with.
2	THE WITNESS: Point 3.	2	BY MR. ZELLERS:
3	A. They found that the	3	 Q. IARC also considered the
4	case-control studies did not demonstrate a	4	Bradford Hill considerations; is that right?
5	consistent positive association across	5	A. Yes, it did.
6	studies; although some studies have found	6	Q. IARC rejected classification of
7	small positive associations between talc and	7	talc as a carcinogenic, instead assigning it
8	ovarian cancer, but lower confidence limits	8	to the classification of possibly
9	are often close to 1, and dose-response	9	carcinogenic to humans; is that correct?
10	evidence is lacking.	10	A. That's correct.
11	BY MR. ZELLERS:	11	Q. We've already discussed the
12	Q. That was FDA's conclusion	12	IARC categories briefly, but let's mark a
13	number 3 based upon its review of the	13	document from the IARC website as to the
14	scientific literature; is that right?	14	classifications, Exhibit 21.
15	MS. O'DELL: Object to the	15	(Carson Deposition Exhibit 21
16	form.	16	marked.)
17	A. It's correct. It's not a valid	17	BY MR. ZELLERS:
	interpretation of the statistical results,	18	Q. Tell me if you recognize that.
18	micipietation of the statistical results,	1	• •
18 19	but that was one of their findings.	19	A. Yes.
	- · · · · · · · · · · · · · · · · · · ·	19 20	A. Yes.Q. Exhibit 21 is from the IARC
19	but that was one of their findings.	1	
19 20	but that was one of their findings. BY MR. ZELLERS:	20	Q. Exhibit 21 is from the IARC
19 20 21	but that was one of their findings. BY MR. ZELLERS: Q. Well, that was their finding.	20 21	Q. Exhibit 21 is from the IARC website, and it goes through the
19 20 21 22	but that was one of their findings. BY MR. ZELLERS: Q. Well, that was their finding. You disagree at least in part with their	20 21 22	Q. Exhibit 21 is from the IARC website, and it goes through the classifications of different agents that have

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	Page 226		Page 228
1		1	MS. O'DELL: Object to the
1 2	A. Yes, that's correct.Q. It has studied and included 120	2	form.
		3	
3 4	agents in the Group 1 category, which is	4	
	carcinogenic to humans, correct?		refers to just the number of studies that
5	A. That's correct.	5	have been performed as well as the quality of
6	Q. That's the only category in	6	the studies.
7	which IARC finds sufficient evidence in	7	BY MR. ZELLERS:
8	humans, correct?	8	Q. Well, based upon the evidence
9	MS. O'DELL: Object to the	9	that is available, the studies that are
10	form.	10	available, a 2B designation by IARC means
11	A. That's the category that	11	that IARC cannot rule out chance, bias or
12	represents substances for which there is	12	confounding with reasonable confidence,
13	sufficient and irrefutable evidence of human	13	correct?
14	carcinogenesis.	14	MS. O'DELL: Objection, asked
15	BY MR. ZELLERS:	15	and answered.
16	Q. It lists 82 agents in Group 2A	16	A. Not always the case.
17	as being probably carcinogenic to humans; is	17	BY MR. ZELLERS:
18	that right?	18	Q. That's part of the definition,
19	A. That's correct.	19	isn't it?
20	Q. IARC is certainly willing to	20	A. I don't believe it applies to
21	declare agents as either a known or probable	21	every agent or every evaluation.
22	carcinogen; is that right?	22	Q. Well, I'll not take the time to
23	A. That's correct.	23	go through the IARC definitions; if we at the
24	Q. There is only one agent in	24	end of the day have extra time, we'll go back
	Daga 227		Daga 220
	Page 227		Page 229
1	Group 4, probably not carcinogenic to humans,	1	and we'll take a look.
2	correct?	2	What else is in the Class 2B,
3	A. Yes. I thought that number had	3	possibly carcinogenic. Ginkgo biloba, is
4	gone up recently, but the date here is	4	that something you're aware of that's in that
5	November 2018, so some may have been moved	5	category?
6	back into Group 3.	6	MS. O'DELL: Object to the
7	Q. So out of the over 1,000 agents	7	form.
8	that IARC has reviewed, it's only placed one	8	A. That's a biological material.
9	agent in the Group 4 category, probably not	9	BY MR. ZELLERS:
10	carcinogenic; is that right?	10	Q. Pickled vegetables?
11	A. That's correct.	11	A. That may be in Group 2B.
12	Q. There is no Group 5, not	12	Q. Occupational carpentry and
13	carcinogenic; is that right?	13	joinery?
14	A. That's correct.	14	MS. O'DELL: Objection to form.
15	Q. With genital talc, IARC	15	A. That's wood dust exposure.
16	Group 2B designation well, strike that.	16	BY MR. ZELLERS:
17	Genital tale is listed as an	17	Q. Also 2B; is that right?
18	IARC Group 2B designated substance; is that	18	A. Wood dust itself is Group 1.
19	right?	19	The occupation is Group 2B.
20	A. That's correct.	20	Q. Let me ask you about some
21	Q. That's based on limited	21	individual Bradford Hill criteria. On
	evidence in humans, which means that IARC	22	page 10 of your report, you state that you
22	evidence in numans, which means that IAIC		page 10 of Joan report, you state that you
22	· · · · · · · · · · · · · · · · · · ·	23	gave the most weight to strength of
22 23 24	cannot rule out chance, bias or confounding with reasonable confidence, correct?	23 24	gave the most weight to strength of association, consistency and biologic

58 (Pages 226 to 229)

	Page 230		Page 232
1	plausibility; is that right?	1	been failed attempts, but they have been
2	A. That's correct.	2	attempts to estimate the quantity of powder
3	Q. How much weight did you give to	3	that you start with and the amount that
4	the other six factors?	4	results in the application to the perineum by
5	A. Sufficient.	5	using models and actually doing some
6	Q. Why did you put less weight on	6	measurements and recording activities.
7	those?	7	BY MR. ZELLERS:
8	A. Because the strength of	8	Q. You did not do any modeling or
9	association, the consistency of the evidence	9	any assessment of the quantity of baby powder
10	and the biological plausibility of perineal	10	that was involved with daily use; is that
11	talc, talcum powder application as	11	right?
12	responsible for the occurrence of ovarian	12	A. No, I relied on those others.
13	cancer was compelling.	13	Q. When you say 30% increased
14	Q. FDA focused on dose, correct?	14	risk, that's a 1.3 odds ratio; is that right?
15	A. Yes.	1 <u>5</u>	A. That's correct.
16	Q. You did not; is that right?	<mark>16</mark>	Q. And that comes largely from the
17	A. That's right.	<mark>17</mark>	case-control studies, correct?
18	Q. The first Bradford Hill factor	18	MS. O'DELL: Object to the
19	that you focused on was strength of	19	form.
20	association.	20	A. Yes, but it's also consistent
21	What association does the	21	with some of the information from the cohort
22	literature report between talc use and	22	studies.
23	ovarian cancer?	23	BY MR. ZELLERS:
24	A. Overall, evaluating the	24	Q. Epidemiologists consider a 1.3
	Page 231		Page 233
1		1	
1 2	universe of research, epidemiologic research	1 2	odds ratio in a case-control study to be a
1 2 3	universe of research, epidemiologic research, that's been done on this, it shows an average	1 2 3	odds ratio in a case-control study to be a weak or modest association; is that right?
1 2 3 4	universe of research, epidemiologic research that's been done on this, it shows an average 30% increase in ovarian cancer risk for those	1 2 3 4	odds ratio in a case-control study to be a
1 2 3 4 5	universe of research, epidemiologic research that's been done on this, it shows an average 30% increase in ovarian cancer risk for those who regularly apply talcum powder to the	1 2 3 4 5	odds ratio in a case-control study to be a weak or modest association; is that right? MS. O'DELL: Object to the form.
1 2 3 4 5	universe of research, epidemiologic research that's been done on this, it shows an average 30% increase in ovarian cancer risk for those	1 2 3 4 5 6	odds ratio in a case-control study to be a weak or modest association; is that right? MS. O'DELL: Object to the
<u>4</u> <u>5</u>	universe of research, epidemiologic research that's been done on this, it shows an average 30% increase in ovarian cancer risk for those who regularly apply talcum powder to the perineum.	2 3 4 5 6 7	odds ratio in a case-control study to be a weak or modest association; is that right? MS. O'DELL: Object to the form. A. That's correct.
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59 (Pages 230 to 233)

	Page 234		Page 236
1	MS. BOCKUS: Excuse me, I need	1	epidemiologists are concerned, correct?
2	to object as nonresponsive.	2	MS. O'DELL: Object to
3	MR. ZELLERS: Yes, join.	3	object to the form.
4	BY MR. ZELLERS:	4	A. It's an increased risk that
5	Q. There is not a consensus at	5	translates into human lives, so it depends on
6	this time with respect to any causation	6	your point of view.
7	relating to genital talc and ovarian cancer,	7	MS. BOCKUS: Object to form
8	is there?	8	I mean, sorry, nonresponsive, move to
9	MS. O'DELL: Objection to the	9	strike.
10	form.	10	MR. ZELLERS: Join.
11	A. I believe that that consensus	11	MS. O'DELL: Oppose.
12	is building.	12	DR. THOMPSON: Agreed.
13	BY MR. ZELLERS:	13	BY MR. ZELLERS:
14	Q. FDA that's not FDA's	14	Q. The 1.3 relative risk that you
15	position, correct?	15	believe generally applies, that would relate
16	MS. O'DELL: Object to the	16	to epithelial cancers; is that right?
17	form.	17	A. Yes.
18	A. Not at the moment.	18	Q. That's what you're limiting
19	BY MR. ZELLERS:	19	your opinions to in this case, correct?
20	Q. That's not the position of the	20	MS. O'DELL: Object to the
21	National Cancer Institute; is that right?	21	form.
22	A. That's correct.	22	A. Well, these opinions relate to
23	Q. That's not the position of the	23	several of the cancers that have shown
24	CDC; is that correct?	24	increases in these background epidemiologic
	CDC, is that correct.		mercuses in mese caexground epideimologie
	Page 235		Page 237
1	Page 235 A. That's correct.	1	Page 237 studies, which include the epithelial ovarian
1 2		1 2	
	A. That's correct.		studies, which include the epithelial ovarian
2	A. That's correct.Q. IARC does not refer to any	2	studies, which include the epithelial ovarian cancers, including the serous; the borderline
2	A. That's correct.Q. IARC does not refer to any association between perineal talc use and	2 3	studies, which include the epithelial ovarian cancers, including the serous; the borderline cancers are also showing increases in some of
2 3 4	A. That's correct. Q. IARC does not refer to any association between perineal talc use and ovarian cancer as a strong association, does	2 3 4	studies, which include the epithelial ovarian cancers, including the serous; the borderline cancers are also showing increases in some of the studies. So it's the group of those
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2 3 4 5 6	A. That's correct. Q. IARC does not refer to any association between perineal talc use and ovarian cancer as a strong association, does it? MS. O'DELL: Object to the	2 3 4 5 6	studies, which include the epithelial ovarian cancers, including the serous; the borderline cancers are also showing increases in some of the studies. So it's the group of those cancers, yes. BY MR. ZELLERS:
2 3 4 5 6 7	A. That's correct. Q. IARC does not refer to any association between perineal talc use and ovarian cancer as a strong association, does it? MS. O'DELL: Object to the form. A. It calls it a Group 2B	2 3 4 5 6 7	studies, which include the epithelial ovarian cancers, including the serous; the borderline cancers are also showing increases in some of the studies. So it's the group of those cancers, yes. BY MR. ZELLERS: Q. The cohort studies, prospective
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	A. That's correct. Q. IARC does not refer to any association between perineal talc use and ovarian cancer as a strong association, does it? MS. O'DELL: Object to the form. A. It calls it a Group 2B carcinogen, which is fairly significant. BY MR. ZELLERS: Q. Well, we discussed a few minutes ago that if an agent is a Group 2B carcinogen, that is based on limited evidence in humans; is that right? A. That's correct. Q. All right. Your opinions on strength of association, do they apply equally to all forms of ovarian cancer? A. No, they don't. These apply to the epithelial ovarian cancer spectrum. Q. Your opinions in terms of there	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	studies, which include the epithelial ovarian cancers, including the serous; the borderline cancers are also showing increases in some of the studies. So it's the group of those cancers, yes. BY MR. ZELLERS: Q. The cohort studies, prospective cohort studies, have not shown an association between talc and ovarian cancer, correct? MS. O'DELL: Object to the form. A. They have in some subtypes. BY MR. ZELLERS: Q. There was an initial description with respect to the first Nurses' study that was not supported in the update of that study; is that correct? A. The Nurses' Health Study? Q. Yes. A. Yes, that's correct. Q. Let's look at a different
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	A. That's correct. Q. IARC does not refer to any association between perineal talc use and ovarian cancer as a strong association, does it? MS. O'DELL: Object to the form. A. It calls it a Group 2B carcinogen, which is fairly significant. BY MR. ZELLERS: Q. Well, we discussed a few minutes ago that if an agent is a Group 2B carcinogen, that is based on limited evidence in humans; is that right? A. That's correct. Q. All right. Your opinions on strength of association, do they apply equally to all forms of ovarian cancer? A. No, they don't. These apply to the epithelial ovarian cancer spectrum.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	studies, which include the epithelial ovarian cancers, including the serous; the borderline cancers are also showing increases in some of the studies. So it's the group of those cancers, yes. BY MR. ZELLERS: Q. The cohort studies, prospective cohort studies, have not shown an association between talc and ovarian cancer, correct? MS. O'DELL: Object to the form. A. They have in some subtypes. BY MR. ZELLERS: Q. There was an initial description with respect to the first Nurses' study that was not supported in the update of that study; is that correct? A. The Nurses' Health Study? Q. Yes. A. Yes, that's correct.

60 (Pages 234 to 237)

	Page 238		Page 240
1	MS. O'DELL: Object to the	1	ill patients in the community to healthy
2	form.	2	people in the community, correct?
3	A. I believe that, in fact,	3	A. In some cases that might be
4	research shows does show a consistent	4	correct, but I'm not sure that's any in
5	pattern.	5	any sort of world an advantage.
6	BY MR. ZELLERS:	6	Q. Well, shouldn't there be
7	Q. The cohort studies do not show	7	consistency if the Bradford Hill criteria is
8	an association between talc use and ovarian	8	to be well, strike that.
9	cancer as we just discussed, correct?	9	In applying the Bradford Hill
10	A. The basic cohort studies that	10	criteria of consistency, there should be
11	look at all of the subjects and all of the	11	consistency across different types of
12	cancers together typically do not rise to the	12	studies, cohort studies, hospital-based
13	level of significance.	13	case-control studies, and population-based
14	Q. The hospital-based case-control	14	case-control studies, correct?
15	studies collectively do not show an	15	
			MS. O'DELL: Object to the
16 17	association between talc use and ovarian	16	form.
	cancer, correct?	17	A. That's correct.
18	A. I sort of discount the	18	BY MR. ZELLERS:
19	distinction between the hospital-based	19	Q. Isn't the absence of an
20	studies and the community-based studies. I'm	20	association in the cohort studies especially
21	not sure whether there are valid reasons to	21	significant in that the study design for the
22	consider those differently.	22	cohort studies reduces the likelihood of
23	Q. We've discussed earlier that	23	recall bias?
24	you are not an epidemiologist; is that right?	24	A. There are many forms of bias
	Page 239		Page 241
1	MS. O'DELL: Object to the	1	that study designers need to consider in the
2	form, misstates his testimony.	1 2 3 4 5 6 7 8	process of designing a study, and there are
3	A. I don't think I necessarily	3	even more types of bias that are discovered
4	agreed to that characterization because I	4	after a study has begun.
5	deal a lot with epidemiologic work. I'm a	5	You can fault case-control
6	faculty member in the Department of	6	studies for being particularly sensitive to
7	Epidemiology at the University of Texas	7	recall bias, but many of these authors who
8	School of Public Health, and some may	8	perform these studies indicated that they
9	consider me an epidemiologist.	9	were well aware of that bias potential and
10	BY MR. ZELLERS:	10	took measures to avoid it.
11		11	The same thing can be said
	O DO VOII COnsider Vourseu an		The same ining can be said
12	Q. Do you consider yourself an expert in epidemiology?		_
12 13	expert in epidemiology?	12	about cohort studies. They suffer from other
13	expert in epidemiology? A. No.	12 13	about cohort studies. They suffer from other forms of bias, misclassification in
13 14	expert in epidemiology? A. No. Q. Do you agree well, do you	12 13 14	about cohort studies. They suffer from other forms of bias, misclassification in particular. They may also suffer from the
13 14 15	expert in epidemiology? A. No. Q. Do you agree well, do you agree that hospital-based case-control	12 13 14 15	about cohort studies. They suffer from other forms of bias, misclassification in particular. They may also suffer from the fact that they are extremely expensive, have
13 14 15 16	expert in epidemiology? A. No. Q. Do you agree well, do you agree that hospital-based case-control studies are less susceptible to selection	12 13 14 15 16	about cohort studies. They suffer from other forms of bias, misclassification in particular. They may also suffer from the fact that they are extremely expensive, have long duration, and require very large numbers
13 14 15 16 17	expert in epidemiology? A. No. Q. Do you agree well, do you agree that hospital-based case-control studies are less susceptible to selection bias than population-based case-control	12 13 14 15 16 17	about cohort studies. They suffer from other forms of bias, misclassification in particular. They may also suffer from the fact that they are extremely expensive, have long duration, and require very large numbers of subjects in order to carry them out and
13 14 15 16 17	expert in epidemiology? A. No. Q. Do you agree well, do you agree that hospital-based case-control studies are less susceptible to selection bias than population-based case-control studies?	12 13 14 15 16 17 18	about cohort studies. They suffer from other forms of bias, misclassification in particular. They may also suffer from the fact that they are extremely expensive, have long duration, and require very large numbers of subjects in order to carry them out and are frequently underpowered and unable to
13 14 15 16 17 18 19	expert in epidemiology? A. No. Q. Do you agree well, do you agree that hospital-based case-control studies are less susceptible to selection bias than population-based case-control studies? A. It depends on the methodology	12 13 14 15 16 17 18 19	about cohort studies. They suffer from other forms of bias, misclassification in particular. They may also suffer from the fact that they are extremely expensive, have long duration, and require very large numbers of subjects in order to carry them out and are frequently underpowered and unable to arrive at the conclusions that they seek for
13 14 15 16 17 18 19 20	expert in epidemiology? A. No. Q. Do you agree well, do you agree that hospital-based case-control studies are less susceptible to selection bias than population-based case-control studies? A. It depends on the methodology that's used to recruit the study subjects.	12 13 14 15 16 17 18 19 20	about cohort studies. They suffer from other forms of bias, misclassification in particular. They may also suffer from the fact that they are extremely expensive, have long duration, and require very large numbers of subjects in order to carry them out and are frequently underpowered and unable to arrive at the conclusions that they seek for that reason.
13 14 15 16 17 18 19 20 21	expert in epidemiology? A. No. Q. Do you agree well, do you agree that hospital-based case-control studies are less susceptible to selection bias than population-based case-control studies? A. It depends on the methodology that's used to recruit the study subjects. Q. With hospital-based	12 13 14 15 16 17 18 19 20 21	about cohort studies. They suffer from other forms of bias, misclassification in particular. They may also suffer from the fact that they are extremely expensive, have long duration, and require very large numbers of subjects in order to carry them out and are frequently underpowered and unable to arrive at the conclusions that they seek for that reason. MR. ZELLERS: Move to strike as
13 14 15 16 17 18 19 20 21	expert in epidemiology? A. No. Q. Do you agree well, do you agree that hospital-based case-control studies are less susceptible to selection bias than population-based case-control studies? A. It depends on the methodology that's used to recruit the study subjects. Q. With hospital-based case-controlled studies, you're more likely	12 13 14 15 16 17 18 19 20 21 22	about cohort studies. They suffer from other forms of bias, misclassification in particular. They may also suffer from the fact that they are extremely expensive, have long duration, and require very large numbers of subjects in order to carry them out and are frequently underpowered and unable to arrive at the conclusions that they seek for that reason. MR. ZELLERS: Move to strike as nonresponsive.
13 14 15 16 17 18 19 20 21 22 23	expert in epidemiology? A. No. Q. Do you agree well, do you agree that hospital-based case-control studies are less susceptible to selection bias than population-based case-control studies? A. It depends on the methodology that's used to recruit the study subjects. Q. With hospital-based case-controlled studies, you're more likely to be comparing hospitalized patients to	12 13 14 15 16 17 18 19 20 21 22 23	about cohort studies. They suffer from other forms of bias, misclassification in particular. They may also suffer from the fact that they are extremely expensive, have long duration, and require very large numbers of subjects in order to carry them out and are frequently underpowered and unable to arrive at the conclusions that they seek for that reason. MR. ZELLERS: Move to strike as nonresponsive. BY MR. ZELLERS:
13 14 15 16 17 18 19 20 21 22	expert in epidemiology? A. No. Q. Do you agree well, do you agree that hospital-based case-control studies are less susceptible to selection bias than population-based case-control studies? A. It depends on the methodology that's used to recruit the study subjects. Q. With hospital-based case-controlled studies, you're more likely	12 13 14 15 16 17 18 19 20 21 22	about cohort studies. They suffer from other forms of bias, misclassification in particular. They may also suffer from the fact that they are extremely expensive, have long duration, and require very large numbers of subjects in order to carry them out and are frequently underpowered and unable to arrive at the conclusions that they seek for that reason. MR. ZELLERS: Move to strike as nonresponsive.

61 (Pages 238 to 241)

	Alch i. Chip Co	x = 0 0 11 ,	M.D., III.D.
	Page 242		Page 244
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	explains the difference between the cohort studies and the retrospective case-control studies? MS. O'DELL: Object to form, asked and answered. A. I don't believe that that is the case. BY MR. ZELLERS: Q. Is it possible? MS. O'DELL: Objection. A. Theoretically it would be possible. BY MR. ZELLERS: Q. Are you familiar with the Berge Berge 2017 study? A. Yes. Q. Is that a study that you cite and reviewed and rely on? A. It was a meta-analysis. Q. Is that a meta-analysis that	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	paragraph. Reading from the second full paragraph, the authors discuss the fact that the association between genital talc use and risk of ovarian cancer is present in case-control but not in cohort studies, can be attributed to bias in the former type of studies; is that right? MS. O'DELL: Object to the form. A. That's what it says. BY MR. ZELLERS: Q. Then continuing down: Information bias from retrospective self-report of talc use is a possible explanation for the association detected in case-control studies. Is that right? A. That's what it says. Q. What was your methodology for discounting the effect of recall bias in the
21 22 23 24	you cite, review and have relied upon? A. Yes. Q. Take a look, if you will, at Exhibit 22.	21 22 23 24	population-based case-control studies? A. The fact that several authors discussed the possibility of recall bias and incorporated methodology for avoiding recall
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	(Carson Deposition Exhibit 22 marked.) THE WITNESS: Thank you. MS. O'DELL: Thank you. BY MR. ZELLERS: Q. You're familiar with this meta-analysis; is that right? A. Yes. Q. The authors conclude that information bias from retrospective self-report of talc use is a possible explanation for the association detected in case-control studies; is that right? MS. O'DELL: I'm sorry, are you reading from a certain page? MR. ZELLERS: I am. MS. O'DELL: Can you direct it to us, please? THE WITNESS: Could you tell us where that is?	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	bias, for example, placing parallel questions that should be affected in the same way, and still showed a positive result for talc and ovarian cancer is one reason. The other has to do with consistency of the results, and although you've stated that from these various documents, including this quotation, that the case-control studies showed positive associations but the cohort studies did not, I would I would refute that by saying that all of the the vast majority of all of the studies show a positive odds ratio or relative risk, even if they don't rise to the level of significance. If these results were obtained simply by chance, you would expect an equal number of positive results and negative results, but we don't have that here. We have practically all positive results with
21 22 23 24	MR. ZELLERS: Sure. BY MR. ZELLERS: Q. Take a look if you will on page 6, the right-hand column, third	21 22 23 24	And so Q. We looked at the Taher paper early on in this deposition where Taher

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	Page 246		Page 248
1	concluded that 15 out of the 30 case-control	1	page.
2	studies reported a statistically significant	2	MS. O'DELL: Object to the
3	association between genital talc use and	3	form.
4	ovarian cancer, correct?	4	BY MR. ZELLERS:
5	A. That's correct, but you're	5	Q. Is that the conclusion of the
6	not you're not talking about the other 15.	6	authors?
7	Q. The hospital-based case-control	7	A. What I'm reading here is on
8	studies collectively do not show a	8	balance, the epidemiological evidence
9	statistically significant association between	9	suggests that the use of cosmetic talc in the
10	talc use and ovarian cancer, correct?	10	perineal area may be associated with ovarian
11	MS. O'DELL: Object to the	11	cancer risk. The mechanism of
12	form.	12	carcinogenicity may be related to
13	A. I don't know that that is the	13	inflammation.
14		14	
15	case. BY MR. ZELLERS:		Q. Take a look at the paragraph on
	1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	15	the right-hand side under Proposal to
16	Q. You don't know that it's not	16	Research Community. I'm looking at the
17	the case; you'd have to go back and relook at	17	second page of the Langseth article.
18	the studies, fair?	18	Are you there?
19	A. I'd have to look through here,	19	A. Yes, I am.
20	which I'm happy to do if you want me to, but	20	Q. The authors state: The current
21	I don't believe that that's the case.	21	body of experimental and epidemiological
22	Q. In fact, the author, you cite	22	evidence is insufficient to establish a
23	the Langseth paper, a 2008 paper, as	23	causal association between perineal use of
24	supportive of your position; is that right?	24	tale and ovarian cancer risk.
	Page 247		Page 249
1	A. Yes.	1	Is that right?
2	Q. I'll mark that	2	MS. O'DELL: Object to the
3	Deposition Exhibit 23.	3	form.
4	A. I think it was 2004, was it	4	A. That's what it says.
5	not?	5	BY MR. ZELLERS:
6	Q. Well, I'm going to hand it to	6	Q. Experimental research is needed
7	you and we can look at it together.	7	to better characterize deposition, retention
8	(Carson Deposition Exhibit 23	8	and clearance of talc to evaluate the ovarian
9	marked.)	9	carcinogenicity of talc.
10	A. Okay.	10	Is that what the authors state?
11	BY MR. ZELLERS:	11	A. Well, that's what it says, but
12	Q. You're familiar with the	12	it says much more. In fact, the editors of
13	Langseth paper; is that right?	13	the journal, in the section on the next page
14	A. Yes.	14	that is titled What This Study Adds, say:
15	(Comments off the stenographic	15	Epidemiological evidence suggests that the
16	record.)	16	use of cosmetic talc in the perineal area may
17	BY MR. ZELLERS:	17	be associated with ovarian cancer risk. The
18	Q. Langseth and the authors	18	IARC has classified this use of talc as
19	concluded that the current body of	19	possibly carcinogenic to human beings,
20	experimental and epidemiological evidence is	20	Group 2B. The mechanism of carcinogenicity
21	insufficient to establish a causal	21	may be related to inflammation. This paper
22	association between perineal use of talc and	22	focused on the high degree of consistency in
23	<u> -</u>	22	
	ovarian cancer risk; is that right?		the studies accomplished so far and what should be the focus in future studies.
24	And I'm looking at the second	24	should be the focus in future studies.
		1	

63 (Pages 246 to 249)

	Page 250		Page 252
1	So I	1	doesn't happen.
2	Q. And then the conclusion is what	2	Q. Is it your testimony that the
3	I read, that: The current body of	3	cohort studies relating to genital talc use
4	experimental and epidemiological evidence is	4	and ovarian cancer are spinning the roulette
5	insufficient to establish a causal	5	wheel?
6		6	
	association between perineal use of talc and	7	MS. O'DELL: Object to the
7	ovarian cancer risk.	1	form.
8	Correct?	8	A. In terms of the power of the
9	MS. O'DELL: Object to the	9	studies to detect a meaningful difference
10	form.	10	among the subjects, yes.
11	A. That is what it says, but this	11	BY MR. ZELLERS:
12	was accepted in 2007, which was now 12 years	12	Q. That's your testimony as an
13	ago.	13	expert in this case; is that right?
14	BY MR. ZELLERS:	14	A. It is my testimony that cohort
15	Q. Let me ask you about the cohort	15	studies, including these, are chronic or
16	studies. They involved a much greater number	16	quite often underpowered simply because of
17	of women than the case-controlled studies; is	17	the expense associated with performing these
18	that right?	18	studies.
19	MS. O'DELL: Object to the	19	Q. What analysis did you do to
20	form.	20	conclude that the cohort studies in this
21	A. Well, they did not involve more	21	area, the four cohort studies, are
22	cases, but they involved more women because	22	underpowered?
23		23	A. Like I just mentioned to you, I
23 24	in order to do a cohort study, you have to start with a huge group of people and wait	23	A. Like I just mentioned to you, I read the studies and looked at their
	in order to do a cohort study, you have to		
	in order to do a cohort study, you have to start with a huge group of people and wait	24	read the studies and looked at their
24	in order to do a cohort study, you have to start with a huge group of people and wait Page 251	24	read the studies and looked at their Page 253
24	in order to do a cohort study, you have to start with a huge group of people and wait Page 251 for them to develop cancers, and then count	24	read the studies and looked at their Page 253 conclusions, and their conclusions were not
1 2 3	in order to do a cohort study, you have to start with a huge group of people and wait Page 251 for them to develop cancers, and then count those cancers. BY MR. ZELLERS:		read the studies and looked at their Page 253 conclusions, and their conclusions were not that the effect didn't exist, but they couldn't detect it.
1 2 3	in order to do a cohort study, you have to start with a huge group of people and wait Page 251 for them to develop cancers, and then count those cancers. BY MR. ZELLERS: Q. What was your methodology for	1 2 3 4	read the studies and looked at their Page 253 conclusions, and their conclusions were not that the effect didn't exist, but they couldn't detect it. MR. ZELLERS: Let's go off the
1 2 3	in order to do a cohort study, you have to start with a huge group of people and wait Page 251 for them to develop cancers, and then count those cancers. BY MR. ZELLERS: Q. What was your methodology for weighing the power of the cohort studies	1 2 3 4 5	read the studies and looked at their Page 253 conclusions, and their conclusions were not that the effect didn't exist, but they couldn't detect it. MR. ZELLERS: Let's go off the record because we need to change our
1 2 3	in order to do a cohort study, you have to start with a huge group of people and wait Page 251 for them to develop cancers, and then count those cancers. BY MR. ZELLERS: Q. What was your methodology for weighing the power of the cohort studies versus the case-control studies?	1 2 3 4	read the studies and looked at their Page 253 conclusions, and their conclusions were not that the effect didn't exist, but they couldn't detect it. MR. ZELLERS: Let's go off the
1 2 3	in order to do a cohort study, you have to start with a huge group of people and wait Page 251 for them to develop cancers, and then count those cancers. BY MR. ZELLERS: Q. What was your methodology for weighing the power of the cohort studies versus the case-control studies? A. The cohort studies, it wasn't	1 2 3 4 5 6	read the studies and looked at their Page 253 conclusions, and their conclusions were not that the effect didn't exist, but they couldn't detect it. MR. ZELLERS: Let's go off the record because we need to change our tape. THE VIDEOGRAPHER: We're off
1 2 3 4 5 6 7	in order to do a cohort study, you have to start with a huge group of people and wait Page 251 for them to develop cancers, and then count those cancers. BY MR. ZELLERS: Q. What was your methodology for weighing the power of the cohort studies versus the case-control studies? A. The cohort studies, it wasn't apparent in every research report exactly how	1 2 3 4 5 6 7	read the studies and looked at their Page 253 conclusions, and their conclusions were not that the effect didn't exist, but they couldn't detect it. MR. ZELLERS: Let's go off the record because we need to change our tape. THE VIDEOGRAPHER: We're off the record at 3:06, end of Tape 3.
1 2 3 4 5 6 7	in order to do a cohort study, you have to start with a huge group of people and wait Page 251 for them to develop cancers, and then count those cancers. BY MR. ZELLERS: Q. What was your methodology for weighing the power of the cohort studies versus the case-control studies? A. The cohort studies, it wasn't apparent in every research report exactly how they had done their sample size calculations	1 2 3 4 5 6 7 8 9	read the studies and looked at their Page 253 conclusions, and their conclusions were not that the effect didn't exist, but they couldn't detect it. MR. ZELLERS: Let's go off the record because we need to change our tape. THE VIDEOGRAPHER: We're off the record at 3:06, end of Tape 3. (Recess taken, 3:06 p.m. to
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64 (Pages 250 to 253)

	Arch I. "Chip" Ca		
	Page 254		Page 256
1	statistically significant association, it	1	front of you?
2	could mean that no risk exists, as we've	2	A. I do.
3	discussed; is that right?	3	I would also add that the
4	A. That's correct.	4	Penninkilampi meta-analysis also found a
5	Q. What methodology did you use to	5	dose-response.
6	weigh the lack of statistical significance	6	Q. Do you mention Penninkilampi at
7	across studies?	7	all in your report?
8	MS. O'DELL: Object to the	8	A. It's cited.
9	form.	9	Q. In the body of your report?
10	A. Across all of the case-control	10	A. I think it's in there
11	studies?	11	somewhere.
12	BY MR. ZELLERS:	12	Q. You believe it is; is that
13	Q. Yes.	13	right?
14	A. I simply treated them as	14	A. I do.
15	isolated research designs that were done on	15	Q. Well, I'll ask you a couple of
16	different populations in different places	16	questions about it then.
17	with different considerations. They were not	17	-
18		18	Before I do, let's talk a
19	necessarily comparable, like apples to apples	19	little bit more about your report. So go to
20	or oranges to oranges; they were very	20	page 7. You state at the very top of that
21	different studies in most cases, and so I	1	page that it has been difficult to estimate
	felt it was important to allow their findings	21	dose in order to evaluate the dose-response
22	to stand on their own.	22	relationship for ovarian cancer; is that
23	Q. I want to talk to you about	23	right?
24	dose-response. That's another of the	24	A. That's correct.
	Page 255		Page 257
1	Bradford Hill criteria; is that right?	1	Q. You state that it also has been
2	A. That's correct.	2	difficult to exactly estimate the quantity of
3	Q. Which studies show a	3	talcum powder administration during personal
4	dose-response, talc exposure and ovarian	4	hygiene activities; is that right?
5 6	cancer?	5	A. That's correct.
6	A. Let me see here. I'm looking	6	Q. Let's look at a couple of the
7	at my notes. The Harlow study from 1992	7	studies that you believe do, in fact, show a
8	showed a dose-response, and the Cramer 2016	8	dose-response. The Penninkilampi, that's a
9	study showed a dose trend with strong odds	9	meta-analysis, 2018; is that right?
10	ratios for premenopausal women and hormone	10	A. That's correct.
11	therapy-treated women with greater than	11	Q. That study does not consider or
12	24 years of exposure.	12	include the Gertic 2010 cohort study; is that
13	The Schildkraut study, also a	13	right?
14	case-controlled study of 2016, showed a	14	A. I I'd have to look at the
15	dose-response.	15	table, but yes, that one may be left out.
16	Q. There are a number of studies	16	Q. Well, that's a significant
17	that did not show a dose-response; is that	17	study to leave out of an analysis, isn't it?
18	right?	18	MS. O'DELL: Object to the
T ()	A. It's correct. They did not	19	form.
10	A HIS COLLECT THEY GIG HOL	1	
19		20	
20	necessarily show there was not a	20	THE WITNESS: I'm getting
20 21	necessarily show there was not a dose-response. They just, as I was	21	there.
20 21 22	necessarily show there was not a dose-response. They just, as I was mentioning before, were unable to detect a	21 22	there. (Document review.)
20 21	necessarily show there was not a dose-response. They just, as I was	21	there.

65 (Pages 254 to 257)

	Page 258		Page 260
1	MS. O'DELL: You need help?	1	Q. This is my highlighted copy, so
2	THE WITNESS: Okay.	2	I'm sure it wasn't yours.
3	BY MR. ZELLERS:	3	A. I'm sorry.
4	Q. And I misspoke. I meant to	4	Q. That's all right. We'll
5	refer to Gates, the updated Nurses' study.	5	take your time.
6	So Gates 2010.	6	A. Here we are.
7	A. Yes, it appears that Gates is	7	Q. Got it, Exhibit 20?
8	not included in the in the spectrum of	8	A. I think so.
9	studies considering; the Gertic study does	9	Q. Do you have the Cramer study in
10	appear.	10	front of you?
11		11	A. I do.
12	Q. Gates 2010 is an important	12	
	cohort study in this area, would you agree?		Q. It's a retrospective
13	MS. O'DELL: Object to the	13	case-control study published in 2016; is that
14	form.	14	right?
15	A. It's important, but I think it	15	A. That's correct.
16	may be considered one of the ones that	16	Q. If we look at the table of
17	suffered from power issues. It wasn't able	17	results on page 337, Table 1.
18	to determine a relative risk in the	18	Do you see that?
19	population that it assessed.	19	A. Yes.
20	BY MR. ZELLERS:	20	Q. This table shows the risk of
21	Q. There are a number of the	21	ovarian cancer for women who use talc, talcum
22	case-control studies that did not determine a	22	powder, daily; is that right?
23	relative risk, at least of statistical	23	MS. O'DELL: Object to the
24	significance, correct?	24	form.
	Page 259		Page 261
1		1	Page 261 A. It does.
1 2	A. Well, they determined odds	1 2	
2	A. Well, they determined odds ratios, which is the equivalent of relative		A. It does. BY MR. ZELLERS:
2	A. Well, they determined odds ratios, which is the equivalent of relative risk for a case-control study.	2	A. It does. BY MR. ZELLERS: Q. And it's four different periods
2 3 4	A. Well, they determined odds ratios, which is the equivalent of relative risk for a case-control study. Q. And in a number of those	2 3	A. It does. BY MR. ZELLERS: Q. And it's four different periods of time; one year, one to five years, five to
2 3 4 5	A. Well, they determined odds ratios, which is the equivalent of relative risk for a case-control study. Q. And in a number of those case-control studies, at least 15 out of the	2 3 4 5	A. It does. BY MR. ZELLERS: Q. And it's four different periods of time; one year, one to five years, five to 20 years and more than 20 years; is that
2 3 4 5 6	A. Well, they determined odds ratios, which is the equivalent of relative risk for a case-control study. Q. And in a number of those case-control studies, at least 15 out of the 30 relative risk was not or strike that	2 3 4 5 6	A. It does. BY MR. ZELLERS: Q. And it's four different periods of time; one year, one to five years, five to 20 years and more than 20 years; is that right?
2 3 4 5 6 7	A. Well, they determined odds ratios, which is the equivalent of relative risk for a case-control study. Q. And in a number of those case-control studies, at least 15 out of the 30 relative risk was not or strike that statistical significance was not achieved in	2 3 4 5 6 7	A. It does. BY MR. ZELLERS: Q. And it's four different periods of time; one year, one to five years, five to 20 years and more than 20 years; is that right? A. That's correct.
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2 3 4 5 6 7 8 9 10 11 12 13	A. Well, they determined odds ratios, which is the equivalent of relative risk for a case-control study. Q. And in a number of those case-control studies, at least 15 out of the 30 relative risk was not or strike that statistical significance was not achieved in the study; is that right? MS. O'DELL: Object to the form. A. That's correct. BY MR. ZELLERS: Q. Let's look at the Cramer paper.	2 3 4 5 6 7 8 9 10 11 12	A. It does. BY MR. ZELLERS: Q. And it's four different periods of time; one year, one to five years, five to 20 years and more than 20 years; is that right? A. That's correct. Q. There was only statistical significance found for the time period of one to five years of use and more than 20 years of use; is that right? A. For the first group, the for those who reported months year of use
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2 3 4 5 6 7 8 9 10 11 12 13 14	A. Well, they determined odds ratios, which is the equivalent of relative risk for a case-control study. Q. And in a number of those case-control studies, at least 15 out of the 30 relative risk was not or strike that statistical significance was not achieved in the study; is that right? MS. O'DELL: Object to the form. A. That's correct. BY MR. ZELLERS: Q. Let's look at the Cramer paper. We've talked about this earlier. A. Which one, the 2016?	2 3 4 5 6 7 8 9 10 11 12 13 14 15	A. It does. BY MR. ZELLERS: Q. And it's four different periods of time; one year, one to five years, five to 20 years and more than 20 years; is that right? A. That's correct. Q. There was only statistical significance found for the time period of one to five years of use and more than 20 years of use; is that right? A. For the first group, the for those who reported months year of use months per year of use. Q. Well, for the first group,
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	A. Well, they determined odds ratios, which is the equivalent of relative risk for a case-control study. Q. And in a number of those case-control studies, at least 15 out of the 30 relative risk was not or strike that statistical significance was not achieved in the study; is that right? MS. O'DELL: Object to the form. A. That's correct. BY MR. ZELLERS: Q. Let's look at the Cramer paper. We've talked about this earlier. A. Which one, the 2016? Q. Exhibit 20, yes, 2016.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	A. It does. BY MR. ZELLERS: Q. And it's four different periods of time; one year, one to five years, five to 20 years and more than 20 years; is that right? A. That's correct. Q. There was only statistical significance found for the time period of one to five years of use and more than 20 years of use; is that right? A. For the first group, the for those who reported months year of use months per year of use. Q. Well, for the first group, which was equivalent to one year of daily
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	A. Well, they determined odds ratios, which is the equivalent of relative risk for a case-control study. Q. And in a number of those case-control studies, at least 15 out of the 30 relative risk was not or strike that statistical significance was not achieved in the study; is that right? MS. O'DELL: Object to the form. A. That's correct. BY MR. ZELLERS: Q. Let's look at the Cramer paper. We've talked about this earlier. A. Which one, the 2016? Q. Exhibit 20, yes, 2016. A. Okay.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	A. It does. BY MR. ZELLERS: Q. And it's four different periods of time; one year, one to five years, five to 20 years and more than 20 years; is that right? A. That's correct. Q. There was only statistical significance found for the time period of one to five years of use and more than 20 years of use; is that right? A. For the first group, the for those who reported months year of use months per year of use. Q. Well, for the first group, which was equivalent to one year of daily use, there was no statistical significance;
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	A. Well, they determined odds ratios, which is the equivalent of relative risk for a case-control study. Q. And in a number of those case-control studies, at least 15 out of the 30 relative risk was not or strike that statistical significance was not achieved in the study; is that right? MS. O'DELL: Object to the form. A. That's correct. BY MR. ZELLERS: Q. Let's look at the Cramer paper. We've talked about this earlier. A. Which one, the 2016? Q. Exhibit 20, yes, 2016. A. Okay. Q. This is another study that you	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	A. It does. BY MR. ZELLERS: Q. And it's four different periods of time; one year, one to five years, five to 20 years and more than 20 years; is that right? A. That's correct. Q. There was only statistical significance found for the time period of one to five years of use and more than 20 years of use; is that right? A. For the first group, the for those who reported months year of use months per year of use. Q. Well, for the first group, which was equivalent to one year of daily use, there was no statistical significance; is that right?
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	A. Well, they determined odds ratios, which is the equivalent of relative risk for a case-control study. Q. And in a number of those case-control studies, at least 15 out of the 30 relative risk was not or strike that statistical significance was not achieved in the study; is that right? MS. O'DELL: Object to the form. A. That's correct. BY MR. ZELLERS: Q. Let's look at the Cramer paper. We've talked about this earlier. A. Which one, the 2016? Q. Exhibit 20, yes, 2016. A. Okay. Q. This is another study that you cite as being supportive of your	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	A. It does. BY MR. ZELLERS: Q. And it's four different periods of time; one year, one to five years, five to 20 years and more than 20 years; is that right? A. That's correct. Q. There was only statistical significance found for the time period of one to five years of use and more than 20 years of use; is that right? A. For the first group, the for those who reported months year of use months per year of use. Q. Well, for the first group, which was equivalent to one year of daily use, there was no statistical significance; is that right? MS. O'DELL: Object to the
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	A. Well, they determined odds ratios, which is the equivalent of relative risk for a case-control study. Q. And in a number of those case-control studies, at least 15 out of the 30 relative risk was not or strike that statistical significance was not achieved in the study; is that right? MS. O'DELL: Object to the form. A. That's correct. BY MR. ZELLERS: Q. Let's look at the Cramer paper. We've talked about this earlier. A. Which one, the 2016? Q. Exhibit 20, yes, 2016. A. Okay. Q. This is another study that you cite as being supportive of your dose-response opinion; is that right?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	A. It does. BY MR. ZELLERS: Q. And it's four different periods of time; one year, one to five years, five to 20 years and more than 20 years; is that right? A. That's correct. Q. There was only statistical significance found for the time period of one to five years of use and more than 20 years of use; is that right? A. For the first group, the for those who reported months year of use months per year of use. Q. Well, for the first group, which was equivalent to one year of daily use, there was no statistical significance; is that right? MS. O'DELL: Object to the form.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	A. Well, they determined odds ratios, which is the equivalent of relative risk for a case-control study. Q. And in a number of those case-control studies, at least 15 out of the 30 relative risk was not or strike that statistical significance was not achieved in the study; is that right? MS. O'DELL: Object to the form. A. That's correct. BY MR. ZELLERS: Q. Let's look at the Cramer paper. We've talked about this earlier. A. Which one, the 2016? Q. Exhibit 20, yes, 2016. A. Okay. Q. This is another study that you cite as being supportive of your dose-response opinion; is that right? A. Yes.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	A. It does. BY MR. ZELLERS: Q. And it's four different periods of time; one year, one to five years, five to 20 years and more than 20 years; is that right? A. That's correct. Q. There was only statistical significance found for the time period of one to five years of use and more than 20 years of use; is that right? A. For the first group, the for those who reported months year of use months per year of use. Q. Well, for the first group, which was equivalent to one year of daily use, there was no statistical significance; is that right? MS. O'DELL: Object to the form. A. That well, the there was
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. Well, they determined odds ratios, which is the equivalent of relative risk for a case-control study. Q. And in a number of those case-control studies, at least 15 out of the 30 relative risk was not or strike that statistical significance was not achieved in the study; is that right? MS. O'DELL: Object to the form. A. That's correct. BY MR. ZELLERS: Q. Let's look at the Cramer paper. We've talked about this earlier. A. Which one, the 2016? Q. Exhibit 20, yes, 2016. A. Okay. Q. This is another study that you cite as being supportive of your dose-response opinion; is that right? A. Yes. Q. Tell me when you have it.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. It does. BY MR. ZELLERS: Q. And it's four different periods of time; one year, one to five years, five to 20 years and more than 20 years; is that right? A. That's correct. Q. There was only statistical significance found for the time period of one to five years of use and more than 20 years of use; is that right? A. For the first group, the for those who reported months year of use months per year of use. Q. Well, for the first group, which was equivalent to one year of daily use, there was no statistical significance; is that right? MS. O'DELL: Object to the form. A. That well, the there was a positive odds ratio with a nonsignificant
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	A. Well, they determined odds ratios, which is the equivalent of relative risk for a case-control study. Q. And in a number of those case-control studies, at least 15 out of the 30 relative risk was not or strike that statistical significance was not achieved in the study; is that right? MS. O'DELL: Object to the form. A. That's correct. BY MR. ZELLERS: Q. Let's look at the Cramer paper. We've talked about this earlier. A. Which one, the 2016? Q. Exhibit 20, yes, 2016. A. Okay. Q. This is another study that you cite as being supportive of your dose-response opinion; is that right? A. Yes.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	A. It does. BY MR. ZELLERS: Q. And it's four different periods of time; one year, one to five years, five to 20 years and more than 20 years; is that right? A. That's correct. Q. There was only statistical significance found for the time period of one to five years of use and more than 20 years of use; is that right? A. For the first group, the for those who reported months year of use months per year of use. Q. Well, for the first group, which was equivalent to one year of daily use, there was no statistical significance; is that right? MS. O'DELL: Object to the form. A. That well, the there was

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	Page 262		Page 264
1	BY MR. ZELLERS:	1	dirty, and it doesn't always work out quite
2	Q. Meaning that if you look at	2	that cleanly.
3	this study, that it is certainly possible	3	BY MR. ZELLERS:
4	that because there is not statistical	4	Q. All right. Do you well, let
5	significance, there could be a finding of no	5	me withdraw that.
6	risk, correct, no increased risk?	6	Confounding. You considered
7	A. That's a possibility.	7	and talk about confounding as another one of
8	Q. Then if we go to the next	8	the Bradford Hill criteria; is that right?
9	period, we do show a dose-response for talcum	9	MS. O'DELL: Object to the
10	powder use in the year years one to five;	10	form.
11	is that right?	11	A. Confounding, by that you mean
12	A. Well, one to five years of	12	specificity?
13	daily use, yes.	13	BY MR. ZELLERS:
14	Q. But then when we look at five	14	Q. Well, I thought your I
15	to 20 years of daily use, there is not a	15	thought you said in your methodology that you
16	statistically significant association; is	16	applied the Bradford Hill criteria.
17	that right?	17	A. That's correct.
18	A. That's correct.	18	O. Is confound strike that.
19	Q. But then when we go to greater	19	Is confounding an issue in
20	than 20 years, we do find a statistical	20	interpreting epidemiologic studies?
21	association; is that right?	21	A. Yes.
22	A. That's correct.	22	Q. Do you agree that there is
23	Q. If, in fact, there was a true	23	confounding in these studies?
24	dose-response relationship, you would expect	24	A. I'm sure there's confounding in
	dose response relationship, you would expect		71. Thi sale there's comountaing in
	Page 263		Page 265
1	to see that dose-response relationship in	1	these studies.
2	each of these groups; is that right?	2	Q. You're familiar with that term,
3	MS. O'DELL: Object to the	3	right?
4	form.	4	A. Yes.
5	A. It's more like we see in the	5	Q. That's where the presence of
6	group directly below that, where you start	6	another association confuses the relationship
7	out with an odds ratio which is not	7	between the exposure and the disease being
8	significant but positive, and then reach a	8	studied; is that right?
9	significant odds ratio at one to five years	9	A. That's correct.
10	of daily use and a higher amount of	10	Q. For example, if you're studying
11	significance with five to 20 years of daily	11	the association between coffee and pancreatic
12	use, and still a significant odds ratio,	12	cancer, you need to be mindful of whether
13	which is about the same level, at greater	13	cigarette smoking is more common in coffee
14	than 20 years of daily use.	14	drinkers than the rest of the population,
15	BY MR. ZELLERS:	15	fair?
16	Q. Is that a yes to my question,	16	A. Yes.
17	that if you do have a true dose-response	17	Q. Coffee or strike that.
18	relationship, you would expect to see that	18	Cigarette smoking could be a
1.0	dose-response continue throughout each of the	19	confounder in that situation?
19	periods?	20	A. Possible.
19 20	P wo .	1	O D :C :C :1:1
	MS. O'DELL: Object to the	21	Q. Because if more coffee drinkers
20	÷	21 22	Q. Because it more coffee drinkers are smokers than non-coffee drinkers, an
20 21	MS. O'DELL: Object to the		· ·

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	Page 266		Page 268
1	smoking, not the coffee drinking; fair?	1	not controlled for in any of the talc/ovarian
2	A. That would be a good	2	cancer studies, were they?
3	description of confounding.	3	A. Not that I'm aware of.
4	Q. Confounding can distort results	4	Q. Are you aware that studies that
5	in epidemiological studies; is that right?	5	show a relationship between tale and ovarian
6	A. It can.	6	cancer did not account for confounders?
7	Q. Do you agree that residual	7	A. I think it's possible that many
8	confounding is possible in every	8	of those studies did not account for all
9	observational study?	9	potential confounders, but they made attempts
10	A. Yes, I think there's some form	10	to.
11	of confounding that's present in every	11	Q. For example, Terry 2013, we
12	observational study.	12	talked about that earlier; is that right?
13	Q. It's possible that unmeasured	13	A. Yes.
14	confounders may be present in every	14	
15		15	
16	observational study; is that right? A. That's correct. Not just	16	did not adjust for hormone replacement
	<u> </u>		therapy usage, correct?
17	unmeasured confounders, but unrecognized	17	A. Yes.
18	confounders.	18	Q. If hormone replacement therapy
19	Q. It's impossible to say that all	19	is a risk factor for ovarian cancer, then the
20	known and unknown confounding factors have	20	Terry 2013 meta-analysis did not account for
21	been controlled for in any given study; is	21	that potential confounding factor, correct?
22	that right?	22	MS. O'DELL: Object to the
23	A. I also agree with that.	23	form.
24	Q. Many new factors possibly	24	A. Correct.
	Page 267		Page 269
1	involved in ovarian cancer risk are just	1	BY MR. ZELLERS:
2	being published in the literature, correct?	2	Q. You cannot say whether the odds
3	MS. O'DELL: Object to the	3	ratio of the Terry 2013 study would have been
4	form.	4	lower if the authors had adjusted for hormone
5	A. I believe that is true.	5	replacement therapy usage, correct?
6	BY MR. ZELLERS:	6	A. I cannot say that. Yes.
7	Q. For example, history of	7	Q. Recall bias. You're familiar
8	chlamydia infection, have you read about that	8	with recall bias?
9	possibly being involved in ovarian cancer	9	A. I am.
10	risk?	10	Q. That is also a concern in every
11	A. I haven't read that	11	retrospective study, correct?
12	specifically. I was thinking more about the	12	A. Yes.
13	new information regarding genetic	13	Q. Recall bias can distort a
14	susceptibilities.	14	scientific evaluation of whether an exposure
15	Q. Also, weight gain during	15	is actually related to a disease; is that
16	adolescence, is that another relatively new	16	right?
	possible ovarian cancer risk factor?	17	A. Yes, it can.
17		18	Q. For example, recall bias could
17 18	MS O'DELL: Object to the	1	distort results if women with ovarian cancer
18	MS. O'DELL: Object to the form	1 1 9	
18 19	form.	19	
18 19 20	form. A. It is, but obesity has been	20	were more likely to remember their exposure
18 19 20 21	form. A. It is, but obesity has been recognized as a cofactor for many years.	20 21	were more likely to remember their exposure to talc than women without ovarian cancer; is
18 19 20 21 22	form. A. It is, but obesity has been recognized as a cofactor for many years. BY MR. ZELLERS:	20 21 22	were more likely to remember their exposure to talc than women without ovarian cancer; is that right?
18 19 20 21	form. A. It is, but obesity has been recognized as a cofactor for many years.	20 21	were more likely to remember their exposure to talc than women without ovarian cancer; is

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1 A. That's correct. 2 BY MR. ZELLERS: 3 Q. The effects of recall bias can 4 be very real; is that right? 4 De very real; is that right? 5 MS. O'DELL: Object to the 6 form. 7 A. I'm not sure what you mean by 8 very real. 9 BY MR. ZELLERS: 10 Q. Well, let's look at one of the 11 studies that you cite. You cited the 12 Schildkraut study in your report and you 13 referred to it a bit earlier as supporting 14 dose-response; is that right? 15 A. Yes. 16 Q. That's a study by Schildkraut 17 and others titled Association Between Body 18 Powder Use and Ovarian Cancer, the 19 African-American Cancer Epidemiologic or 20 Epidemiology Study. 21 Is that right? 22 A. Yes. 23 Q. I've got it here for you. 24 A. Okay. 2 publicity from lawsuits might influence participants' recall of prior body powde use; is that right? 4 A. This was a recent study, so that was more likely. 6 Q. If you look on page 2, 7 right-hand side, last paragraph that start "Covariates include." 9 Do you see that? 10 A. Yes. 11 Subject to the 12 Q. And I'm reading about two-thirds of the way down: Two class always were filed in 2014 concerning possible carcinogenic effects of body promise therefore, year of interview 2014 or late yes/no, was concluded as a covariate in logistic regression models. 15 Is that correct? 16 Q. So go to page 4, Table 2. This is the adjusted odds ratio for the associations between mode, frequency aduration of body powder use in ovarian	272
2 BY MR. ZELLERS: 3 Q. The effects of recall bias can 4 be very real; is that right? 5 MS. O'DELL: Object to the 6 form. 6 A. I'm not sure what you mean by 7 very real. 8 very real. 9 BY MR. ZELLERS: 9 Do you see that? 10 Q. Well, let's look at one of the 11 studies that you cite. You cited the 11 studies that you cite. You cited the 11 Schildkraut study in your report and you 12 referred to it a bit earlier as supporting 13 dose-response; is that right? 14 A. Yes. 15 A. Yes. 16 Q. That's a study by Schildkraut 17 and others titled Association Between Body 18 Powder Use and Ovarian Cancer, the 19 African-American Cancer Epidemiologic or 20 Epidemiology Study. 21 Is that right? 22 A. Yes. 23 Q. I've got it here for you. 24 A. Okay. Page 271 1 (Carson Deposition Exhibit 24 marked.) 3 BY MR. ZELLERS: 9 Do you see that? A. Yes. 15 who thirds of the way down: Two class lawsuits were filed in 2014 concerning possible carcinogenic effects of body powder use and Ovarian Cancer. the 18 logistic regression models. 18 that correct? 20 Epidemiology Study. 21 Is that right? 22 A. Yes. 23 Q. I've got it here for you. 24 A. Okay. Page 271 1 (Carson Deposition Exhibit 24 marked.) 3 BY MR. ZELLERS: 4 Q. Deposition Exhibit 24 is the 5 Schildkraut study, 2016, correct? 6 (Pause.) 6 (Pause.) 6 (Pause.) 7 BY MR. ZELLERS: 7 Q. The third column shows the 20 Colon pide that right? 21 A. Yes. 22 (D. That's all right. I may have 23 (D. That's all right. I may have 24 (D. Looking at this data before 25 (D. Looking at this data before acours, said they used talc on their genital cancer, said they used talc on their genital cancer, said they used talc on their genital cancer.	272
4 be very real; is that right? 5 MS. O'DELL: Object to the 6 form. 6 A. I'm not sure what you mean by 8 very real. 9 BY MR. ZELLERS: 10 Q. Well, let's look at one of the 11 studies that you cite. You cited the 12 Schildkraut study in your report and you 13 referred to it a bit earlier as supporting 14 dose-response; is that right? 15 A. Yes. 16 Q. That's a study by Schildkraut 17 and others titled Association Between Body 18 Powder Use and Ovarian Cancer, the 19 African-American Cancer Epidemiologic or 20 Epidemiology Study. 21 Is that right? 22 A. Yes. 23 Q. I've got it here for you. 24 A. Okay. Page 271 Page 271 (Carson Deposition Exhibit 24 marked.) 3 BY MR. ZELLERS: 4 Q. Deposition Exhibit 24 is the 5 Schildkraut study, 2016, correct? 6 (Pause.) 6 MS. O'DELL: Object to the 5 that was a recent study, so that was a recent study, so that was more likely. 4 A. Yes. 10 A. This was a recent study, so that was more likely. Q. If you look on page 2, right-hand side, last paragraph that start was that was more likely. Q. Ind' you look on page 2, right-hand side, last paragraph that start was that was more likely. Q. And I'm reading about two-thirds of the way down: Two class two-thirds of the way down: Two class the work in two-thirds of the way down: Two class the work in two-thirds of the way down: Two class the two-thirds of the way down: Two class the work in two-thirds of the way down: Two class the work in two-thirds of the way down: Two class the work in two-thirds of the way down: Two class two-thirds of the way down: Two class "Covariates include." 9 A. Yes. 15 A. Yes. 16 Q. That's a study by Schildkraut 17 and others titled Association Between Body 18 powder Use and Ovarian Cancer, the logical carcinogenic effects of body powder use in vorian logicarcinogenic effects of body powder use in vorian logicarcinogenic effects of body powder use in vorian cancer; is that right? 1	
be very real; is that right? MS. O'DELL: Object to the form. A. I'm not sure what you mean by very real. BY MR. ZELLERS: Q. Well, let's look at one of the studies that you cite. You cited the subject of the studies that you cite. You cited the studies that you cite. You cited the studies that you cite. You cited the subject of the studies that you cite. You cited the subject of the studies that you cite. You cited the subject of the subject of the way down: Two class a lawsuits were filed a 2014 concerning possible carcinogenic effects of body possible and others titled Association Between Body possible carcinogenic effects of body possible carcinogenic effects of body possible and others titled Association Between Body possible carcinogenic effects of body possible carcinogenic eff	
5 MS. O'DELL: Object to the form. 6 form. 7 A. I'm not sure what you mean by very real. 8 very real. 9 BY MR. ZELLERS: 10 Q. Well, let's look at one of the 11 tsudies that you cite. You cited the 12 Schildkraut study in your report and you 12 two-thirds of the way down: Two class lawsuits were filed in 2014 concerning 4 dose-response; is that right? 15 A. Yes. 16 Q. That's a study by Schildkraut 16 therefore, year of interview 2014 or late yes/no, was concluded as a covariate in logistic regression models. 17 and others titled Association Between Body 18 Powder Use and Ovarian Cancer, the 19 African-American Cancer Epidemiologic or 20 Epidemiology Study. 21 Is that right? 22 A. Yes. 23 Q. I've got it here for you. 24 A. Okay. 25 O. Deposition Exhibit 24 marked.) 26 Deposition Exhibit 24 is the 5 Schildkraut study, 2016, correct? 27 BY MR. ZELLERS: 38 Q. Deposition Exhibit 24 is the 5 Schildkraut study, 2016, correct? 49 A. I think I did. I'm sorry. 50 Q. That's all right. I may have 10 A. Yes. 51 Q. Looking at this data before 2014, before the lawsuits, the percentage 11 missed it. 52 Controls, main graph that start was more likely. 53 Chaldkraut study on the surface with start was more likely. 54 Covariates include." 55 Covariates include." 66 O. A. That's and the swal down: Two class lawsuits were filed in 2014 concerning possible carcinogenic effects of body peositie earcinogenic effects of body peositie carcinogenic effects of body peositie carcinogenic effects of body peositie carcinogenic effects of body peositie earcinogenic effects of body peositie earcinogenic effects of body peositie carc	
form. A. I'm not sure what you mean by 8 very real. BY MR. ZELLERS: 9 Do you see that? 10 Q. Well, let's look at one of the 11 studies that you cite. You cited the 12 Schildkraut study in your report and you 13 referred to it a bit earlier as supporting 14 dose-response; is that right? 15 A. Yes. 16 Q. That's a study by Schildkraut 17 and others titled Association Between Body 18 Powder Use and Ovarian Cancer, the 19 African-American Cancer Epidemiologic or 20 Epidemiology Study. 21 Is that right? 22 A. Yes. 23 Q. I've got it here for you. 24 A. Okay. Page 271 1 (Carson Deposition Exhibit 24 2 marked.) 3 BY MR. ZELLERS: 4 Q. Deposition Exhibit 24 is the 5 Schildkraut study, 2016, correct? 6 (Pause.) 6 (Pause.) 7 BY MR. ZELLERS: 8 Q. Did you say correct? 9 A. I think I did. I'm sorry. 10 Q. That's all right. I may have 11 missed it. 12 Exhibit 24 is the Schildkraut 13 missed it. 14 C. Yes. 15 Q. Looking at this data before 16 Q. That's alt right? 17 cancer, said they used tale on their genital 18 controls, main gide, last paragraph that start start include." 19 Do you see that? 10 A. Yes. 11 wo thirds of the way down: Two class lawsuits were filed in 2014 concerning possible carcinogenic effects of body p 12 two-thirds of the way down: Two class lawsuits were filed in 2014 concerning possible carcinogenic effects of body p 14 three-fore, year of interview 2014 or late therefore, year of	
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7 Q. The third column shows the 8 Q. Did you say correct? 8 controls; that's the women who do not have 9 A. I think I did. I'm sorry. 9 ovarian cancer, correct? 10 Q. That's all right. I may have 10 A. Yes. 11 missed it. 11 Q. Looking at this data before 12 Exhibit 24 is the Schildkraut 12 2014, before the lawsuits, the percentage 13 2016 study; is that right? 13 controls, meaning women without ovarian 14 A. Yes. 14 cancer, said they used talc on their genital	
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 2016 study; is that right? A. Yes. controls, meaning women without ovariant cancer, said they used talk on their genital 	of
14 A. Yes. 14 cancer, said they used talc on their genital	
15 O. This is one of the studies that 1 15 was 54% is that right?	
you cite to and that you relied on in forming 16 So those are women who were	
your opinions; is that right? 17 interviewed before 2014.	
18 A. Yes. 18 A. Yes. Any genital use controls,	
19 Q. The study looked at, among 19 34%.	
20 other things, what impact, if any, lawsuit 20 Q. And the controls, again, are	
21 filings in 2014 had on whether women recalled 21 women without ovarian cancer.	
22 using talc in the past, correct? 22 A. That's correct.	
23 A. I believe so. 23 Q. The percentage of cases,	
	were
Q. The authors thought that the 24 meaning women with ovarian cancer, that	WEIG

69 (Pages 270 to 273)

	Page 274		Page 276
1	interviewed before 2014 that said they used	1	BY MR. ZELLERS:
2	talc on their genitals was 36.5%; is that	2	Q. In this study, lawsuit filings
3	right?	3	appears to have affected how many women with
4	A. That's correct.	4	ovarian cancer remembered using talc on their
5	Q. So roughly the same reporting	5	genitals but basically had no effect on the
6	of genital talc use between women with and	6	memory of women without ovarian cancer; is
7	without ovarian cancer occurred for those	7	that right?
8	women interviewed before the lawsuits were	8	MS. O'DELL: Object to the
9	filed; is that right?	9	form.
10	A. That's correct.	10	A. You can't say that this is
11	Q. Then look at what happened	11	this demonstrates recall bias. It could.
12	after the lawsuits were filed in 2014. For	12	BY MR. ZELLERS:
13	women interviewed after 2014, the percent of	13	Q. These findings could be an
14	women without ovarian cancer that said they	14	example of the potential effect of recall
15	used talc on their genitals was 34.4%; is	15	bias; is that right?
16	that right?	16	MS. O'DELL: Object to the
17	A. That's correct.	17	form.
18	Q. So based on this data, the	18	A. That is correct.
19	lawsuits had essentially no effect on how	19	BY MR. ZELLERS:
20	many of the women without ovarian cancer, the	20	Q. So pre-2014 there was an odds
21	controls, remembered or recalled using baby	21	ratio of 1.19 with the confidence interval
22	powder; is that right?	22	ranging from .87 to strike that
23	A. Well, the percentage is the	23	from .87 to 1.63, so there is not statistical
24	same in both cases.	24	significance pre-2014; is that right?
	Page 275		Page 277
1	Q. It went from 34% to 34.4%; is	1	A. Probably not.
2	that right?	2	Q. If the study had been
3	A. That's correct.	3	terminated as of 2014, prior to the lawsuits
4	Q. For women with ovarian cancer,	4	being filed, then the results of the study
5	before the lawsuits were filed, 36.5% of them	5	would have been that genital talc use was not
6	said they recalled using baby powder; is that	6	statistically significantly associated with
7	right?	7	an increased risk of ovarian cancer; is that
8	A. That's right.	8	right?
9	Q. But after the lawsuits were	9	MS. O'DELL: Object to the
10	filed, the percent of women with ovarian	10	form.
11	cancer who said they used baby powder went up	11	A. Yes.
12	to 51.5%; is that right?	12	BY MR. ZELLERS:
13	A. That is also correct.	13 14	Q. Did you make an attempt to
14	Q. Is that a significant increase		account for this potential recall bias in
15 16	from 36.5%?	15 16	weighing the Schildkraut study? A. The authors did that for me by
16 17	A. I don't know, but it seems like	17	including the period of the interview as a
17 18	it might be.	18	cofactor in the logistic regression models.
18 19	Q. So after the lawsuits were filed, the percent of women with ovarian	19	It accounts for this difference that you see
20	cancer who said they used baby powder jumped	20	on the table.
21	significantly; is that right?	21	Q. You do agree there was no
22	MS. O'DELL: Object to the	22	statistically significant finding of an odds
23	form.	23	ratio prior to 2014, the data collected
23		1	through that time; is that right?
24	A. Well, that's that is true.	24	through that time; is that right?

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A. In the — in the data collected on those — let me see here. In the data collected on those — let me see here. In the data collected on those — let me see here. In the data collected on those 51 cases and corresponding controls, there was not a significant odds ratio. 4		Page 278		Page 280
on those — let me see here. In the data collected on those 351 cases and corresponding controls, there was not a significant odds ratio. Q. I vant tog boak and ask you a few questions about some of the things I had talked to you before about. In terms of this chatter about I LARC, who has told you this? I A. There are a number of environmental websites and — that also operate on social media that discuss this did for thing. Q. So there's social media websites that have talked about at least the possibility of IARC revisiting the issue? I A. Yes, among many other things. I A. Yes, and you believe that comstarch is rapidly cleared from the body, including the ovaries; is that right? A. Yes. BY MR. ZFLLERS: Q. What is the mechanism by which you believe that comstarch is rapidly cleared from the body, including the ovaries; is that a small amount of carbohydrate with a small amount of structural material, probably cellulose, and those materials are broken down in body for carbohydrate with a small amount of structural material, probably cellulose, and those materials are broken down in body period for ovarian cancer is between 20 and 40 years; is that right? A. Yes. Q. You testified that the latency period for and includes on the incidence data and what is known about the hat talked on the incidence data and what is known about the hat talked on the incidence data and what is known about the hat talked to you affer about exactly where I determined the latency period for for be between 20 and 40 years. We do have a paper that's determined the latency period for and includes ovarian cancer as one of the tumors that it determined the latency period for and includes ovarian cancer as one of the tumors that it uses a mathematical formula with various factors plugged into it to calculate that. In that particular article, the latency period for and it uses a mathematical formula with various factors plugged into it to calculate that. In that particular article, the special propers of the sunding a mathematical formul	1	A. In the in the data collected	1	
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Page 279 Page 279 A. Yes. BY MR. ZELLERS: Q. What is the mechanism by which you believe that cornstarch is rapidly cleared from the body, including the ovaries? A. It's primarily composed of carbohydrate with a small amount of structural material, probably cellulose, and those materials are broken down in body fluids fairly rapidly and dissolved and become part of the general milieu of the body. Q. Does cornstarch create inflammation in the body? A. Yes. Q. You are recalling that at least in some of the study or studies that you've reviewed that the latency period for ovarian cancer is 20 to 40 years, correct? A. Yes. Q. Are you able to tell us which study or studies you're relying on for that information? A. I'd have to go through my list to find it. Do you mind if I take a moment to do that? Q. You testified that the latency period for ovarian cancer is between 20 and 40 years; is that right? A. Roughly, yes. Q. What is the basis for you saying that? A. There are a number of factors 22 period for ovarian cancer is something you've written out in one of your handwritten notes?	23	MS. O'DELL: Object to the	23	A. I have I've calculated
1 A. Yes. 2 BY MR. ZELLERS: 3 Q. What is the mechanism by which 4 you believe that cornstarch is rapidly 5 cleared from the body, including the ovaries? 6 A. It's primarily composed of 7 carbohydrate with a small amount of 8 structural material, probably cellulose, and 9 those materials are broken down in body 10 fluids fairly rapidly and dissolved and 11 become part of the general milieu of the 12 body. 13 Q. Does cornstarch create 14 inflammation in the body? 15 A. Yes. 16 Q. You testified that the latency 17 period for ovarian cancer is between 20 and 18 40 years; is that right? 19 A. Roughly, yes. 20 Q. What is the mechanism by which 21 saying that? 22 A. There are a number of factors 23 graduate school, but that's not something I normally do. I usually defer to the those who have published latency periods for that information. 2 mormally do. I usually defer to the those who have published latency periods for that information. 3 who have published latency periods for that information. 4 information. 4 information. 7 reviewed that the latency period for ovarian cancer is 20 to 40 years, correct? 8 A. Yes. 9 Q. Are you able to tell us which study or studies you're relying on for that information? 9 A. I'd have to go through my list to find it. Do you mind if I take a moment to do that? 9 Q. Define "a moment." 9 A. Well, however long it takes me to find it in that list, but 9 Q. What is the basis for you 9 Q. Let me see if I can shortcut it. 9 Do you believe that the latency period for ovarian cancer is something you've written out in one of your handwritten notes?	24	form.	24	latency periods as an exercise when I was in
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12 body. 13 Q. Does cornstarch create 14 inflammation in the body? 15 A. Yes. 16 Q. You testified that the latency 17 period for ovarian cancer is between 20 and 18 40 years; is that right? 19 A. Roughly, yes. 20 Q. What is the basis for you 21 saying that? 22 A. There are a number of factors 23 that influence that, but there are 20 Information? 21 Information? 22 information? 23 information? A. I'd have to go through my list to find it. Do you mind if I take a moment 29 Q. Define "a moment." 20 A. Well, however long it takes me 20 to find it in that list, but 21 Q. Let me see if I can shortcut 22 period for ovarian cancer is something you've 23 written out in one of your handwritten notes?	10	fluids fairly rapidly and dissolved and	10	Q. Are you able to tell us which
Q. Does cornstarch create 13 A. I'd have to go through my list 14 inflammation in the body? 15 A. Yes. 16 Q. You testified that the latency 17 period for ovarian cancer is between 20 and 18 40 years; is that right? 19 A. Roughly, yes. 19 Q. What is the basis for you 20 Q. What is the basis for you 21 saying that? 22 A. There are a number of factors 23 that influence that, but there are 24 to find it. Do you mind if I take a moment 26 to do that? 27 Q. Define "a moment." 28 A. Well, however long it takes me 29 to find it in that list, but			l	
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A. Yes. Q. You testified that the latency 16 Q. Define "a moment." A. Well, however long it takes me 18 40 years; is that right? A. Roughly, yes. 19 Q. Let me see if I can shortcut 20 Q. What is the basis for you 21 saying that? 22 A. There are a number of factors 23 that influence that, but there are 25 to do that? Q. Define "a moment." A. Well, however long it takes me 26 to find it in that list, but 27 Q. Let me see if I can shortcut 28 Do you believe that the latency 29 period for ovarian cancer is something you've 20 written out in one of your handwritten notes?		•	l	
Q. You testified that the latency period for ovarian cancer is between 20 and 40 years; is that right? A. Roughly, yes. Q. Define "a moment." A. Well, however long it takes me to find it in that list, but Q. Let me see if I can shortcut Q. What is the basis for you saying that? A. There are a number of factors A. There are a number of factors written out in one of your handwritten notes?			l	
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18 40 years; is that right? 19 A. Roughly, yes. 20 Q. What is the basis for you 21 saying that? 22 A. There are a number of factors 23 that influence that, but there are 18 to find it in that list, but Q. Let me see if I can shortcut 20 it. 21 Do you believe that the latency 22 period for ovarian cancer is something you've 23 written out in one of your handwritten notes?			l	
A. Roughly, yes. Q. What is the basis for you Saying that? A. There are a number of factors that influence that, but there are 20 Do you believe that the latency period for ovarian cancer is something you've written out in one of your handwritten notes?			l	
Q. What is the basis for you 20 it. 21 saying that? 22 A. There are a number of factors 23 that influence that, but there are 20 it. 21 Do you believe that the latency 22 period for ovarian cancer is something you've 23 written out in one of your handwritten notes?			l	
saying that? 21 Do you believe that the latency 22 A. There are a number of factors 23 that influence that, but there are 24 period for ovarian cancer is something you've 25 written out in one of your handwritten notes?				
A. There are a number of factors 22 period for ovarian cancer is something you've that influence that, but there are 23 written out in one of your handwritten notes?		· · · · · · · · · · · · · · · · · · ·	l	
that influence that, but there are 23 written out in one of your handwritten notes?		saying that?		
· · · · · · · · · · · · · · · · · · ·		· . ·		
organizations that have determined latency 24 A. I don't believe so.	22		l	· · · · · · · · · · · · · · · · · · ·
	22 23	that influence that, but there are	23	written out in one of your handwritten notes?

71 (Pages 278 to 281)

	D 000		5 004
	Page 282		Page 284
1	Q. It would be where would it	1	MS. BOCKUS: If you want to
2	be?	2	pass me your microphone, I think I can
3	MS. O'DELL: If you need a	3	stay here. I'm not going to pass him
4	moment to review either your report or	4	that many exhibits.
5	your materials list, you know	5	MR. ZELLERS: I'm happy to help
6	THE WITNESS: I don't believe	6	you.
7	that particular piece of information	7	MS. BOCKUS: Thank you.
8	is in my report, but it's I think I	8	EXAMINATION
9	could come up with it fairly quickly	9	BY MS. BOCKUS:
10	if I	10	Q. Dr. Carson, my name is Jane
11	BY MR. ZELLERS:	11	Bockus. I'm not certain I actually
12	Q. All right. Go ahead. Find for	12	introduced myself to you this morning, but I
13	us the study or studies you're relying on for	13	represent Imerys in this litigation.
14	the latency period of ovarian cancer.	14	Do you understand that?
15	A. Okay. If I'm lucky, I may hit	15	A. I do.
16	on it here.	16	Q. Before Mr. Abney contacted you
17	(Document review.)	17	about preparing a report that would explain
18	A. It's the Diana Nadler and Igor	18	the relationship between regular perineal use
19	Zurbenko paper Estimating Cancer Latency	19	of talc based on personal hygiene products
20	Times Using the Weibull Model.	20	and subsequent development of ovarian cancer,
21	BY MR. ZELLERS:	21	is that anything that you had researched
22	Q. You're looking at Exhibit 4,	22	before that date?
23	your literature list; is that right?	23	MS. O'DELL: Object to the
24	A. Yes.	24	form.
	Page 283		Page 285
1	Q. What page of Exhibit 4 are you	1	A. I don't think Mr. Abney
2	looking at?	2	well, he may have been that detailed in our
3	A. Page 17 in the Ns.	3	discussion. But in response to your
4	Q. Are you finished?	4	question, that's not a specific question I
5	A. There may be others in the	5	had researched in the past, although I had
6	list, but you asked me to cite one. You want	6	researched related kinds of issues.
7	me to continue looking?	7	BY MS. BOCKUS:
8	Q. No, I that is sufficient for	8	Q. So would it be fair to say that
9	my purposes. Thank you.	9	the opinions contained in your report are all
10	Dr. Carson, there have been	10	opinions that you have come to as a result of
11	some studies where talc particles had been	11	doing the research at the request of
12	observed or reported in the ovaries of women	12	Mr. Abney and others in the plaintiffs'
13	who have had perineal talc use; is that	13	lawyer group?
14	right?	14	MS. O'DELL: Object to the
	A. Yes.	15	form.
15		1	
15 16	Q. Heller was one of the studies	16	A. Yes.
		16 17	A. Yes. BY MS. BOCKUS:
16	Q. Heller was one of the studies	1	
16 17	Q. Heller was one of the studies that we talked about, correct?	17	BY MS. BOCKUS:
16 17 18	Q. Heller was one of the studies that we talked about, correct?A. Correct.	17 18	BY MS. BOCKUS: Q. Okay. And I'm going to apologize right now. I'll be jumping around
16 17 18 19	Q. Heller was one of the studies that we talked about, correct?A. Correct.Q. In those studies, there has not been inflammation noted; is that right?	17 18 19	BY MS. BOCKUS: Q. Okay. And I'm going to apologize right now. I'll be jumping around because most of my outline has already been
16 17 18 19 20	Q. Heller was one of the studies that we talked about, correct?A. Correct.Q. In those studies, there has not been inflammation noted; is that right?	17 18 19 20	BY MS. BOCKUS: Q. Okay. And I'm going to apologize right now. I'll be jumping around because most of my outline has already been covered, so let me just get you to look at
16 17 18 19 20 21	 Q. Heller was one of the studies that we talked about, correct? A. Correct. Q. In those studies, there has not been inflammation noted; is that right? A. No, there that's not been an 	17 18 19 20 21	BY MS. BOCKUS: Q. Okay. And I'm going to apologize right now. I'll be jumping around because most of my outline has already been

72 (Pages 282 to 285)

	Page 286		Page 288
1	paragraph (b), the first sentence reads:	1	A. No.
2	Numerous studies have examined the	2	Q. And then going on, you talk
3	cancer-causing characteristics of talc.	3	about the fact that there in that same
4	Do you see that?	4	paragraph, if you go down, you talk about
5	A. Yes.	5	IARC and the fact that IARC concluded that
6	Q. And you identified Wilde as	6	talcum powder use by women for feminine
7	your source for that statement, correct?	7	hygiene is a possible human carcinogen;
8	A. That is correct.	8	that's not a classification of talc as a
9	Q. Isn't it correct that the Wild	9	carcinogen, correct?
10	study actually exonerated tale as having	10	MS. O'DELL: Object to the
11	cancer-causing characteristics?	11	form.
12	A. That was a conclusion of the	12	A. It is within the spectrum of
13	author, but the reason it's cited there is	13	carcinogens.
14	because that's an example of the	14	BY MS. BOCKUS:
15		15	
16	investigation of the relationship. Q. Okay. But in that study,	16	Q. It's possible.A. That's correct.
17	Q. Okay. But in that study, they he concluded that talc alone did not	17	Q. And then you say that
18	cause cancer, correct?	18	meaning that there is insufficient evidence
19		19	of carcinogenesis in humans, but strong
20	A. As I recall, that was the	20	
	general conclusion, yes.	21	evidence in other mammalian species.
21 22	Q. Okay. Then in the next couple	22	Can you tell me where in IARC
23	of sentences, you say that talc has caused	23	it says that there is strong evidence that tale causes ovarian cancer in other mammalian
23 24	cancer when implanted in various tissues and	24	
24	under the skin in laboratory animals. It	24	species?
	Page 287		Page 289
1	causes inflammation and fibrotic reaction,	1	A. I think the issue is not
2	including the chemotaxis of inflammatory	2	specifically ovarian cancer; the issue is
3	immune cells and accelerated growth and	3	cancer. And that's the point of view of
4	division of cells in the involved tissue.	4	IARC, and that's what's alluded to here.
5	And you cite Okada 2007 for	5	Q. So this is the one exhibit I'm
6	that proposition; is that correct?	6	going to hand you, if I can get that one
7	A. That's correct.	7	marked by my assistant.
8	Q. But Okada wasn't even looking	8	MR. ZELLERS: Exhibit 25.
9	at talc, was it?	9	(Carson Deposition Exhibit 25
10	A. Let me see here. Okada was	10	marked.)
11	looking at inflammation as as the endpoint	11	MS. O'DELL: This is a page out
12	in the various components of inflammation	12	of the monograph?
13	which I talked about here, the chemotaxis of	13	MS. BOCKUS: Yes.
14	inflammatory immune cells, accelerated growth	14	MS. O'DELL: Are you going to
14 15	division in the involved tissues.	15	identify it?
14	division in the involved tissues. Q. But what you say is that talc	15 16	identify it? MS. BOCKUS: And he can look it
14 15	division in the involved tissues. Q. But what you say is that talc causes. When you say "it," you're referring	15 16 17	identify it? MS. BOCKUS: And he can look it up in his whole monograph. I just
14 15 16	division in the involved tissues. Q. But what you say is that talc causes. When you say "it," you're referring to talc, correct? It causes inflammation and	15 16 17 18	identify it? MS. BOCKUS: And he can look it up in his whole monograph. I just pulled the page for simplicity.
14 15 16 17	division in the involved tissues. Q. But what you say is that talc causes. When you say "it," you're referring to talc, correct? It causes inflammation and fibrotic reaction; isn't that what you're	15 16 17 18 19	identify it? MS. BOCKUS: And he can look it up in his whole monograph. I just pulled the page for simplicity. MS. O'DELL: So feel free to do
14 15 16 17 18	division in the involved tissues. Q. But what you say is that talc causes. When you say "it," you're referring to talc, correct? It causes inflammation and fibrotic reaction; isn't that what you're saying in this sentence?	15 16 17 18 19 20	identify it? MS. BOCKUS: And he can look it up in his whole monograph. I just pulled the page for simplicity. MS. O'DELL: So feel free to do that, Doctor.
14 15 16 17 18	division in the involved tissues. Q. But what you say is that talc causes. When you say "it," you're referring to talc, correct? It causes inflammation and fibrotic reaction; isn't that what you're	15 16 17 18 19 20 21	identify it? MS. BOCKUS: And he can look it up in his whole monograph. I just pulled the page for simplicity. MS. O'DELL: So feel free to do that, Doctor. MS. BOCKUS: Yes, page 412.
14 15 16 17 18 19	division in the involved tissues. Q. But what you say is that talc causes. When you say "it," you're referring to talc, correct? It causes inflammation and fibrotic reaction; isn't that what you're saying in this sentence?	15 16 17 18 19 20 21 22	identify it? MS. BOCKUS: And he can look it up in his whole monograph. I just pulled the page for simplicity. MS. O'DELL: So feel free to do that, Doctor. MS. BOCKUS: Yes, page 412. BY MS. BOCKUS:
14 15 16 17 18 19 20 21	division in the involved tissues. Q. But what you say is that talc causes. When you say "it," you're referring to talc, correct? It causes inflammation and fibrotic reaction; isn't that what you're saying in this sentence? A. It is talc, yes.	15 16 17 18 19 20 21	identify it? MS. BOCKUS: And he can look it up in his whole monograph. I just pulled the page for simplicity. MS. O'DELL: So feel free to do that, Doctor. MS. BOCKUS: Yes, page 412.

73 (Pages 286 to 289)

	Page 290		Page 292
1	talks about the data the evidence that	1	black, titanium dioxide and talc.
2	they have and the evidence that they	2	So regarding talc, the overall
3	reviewed.	3	point of view here is whether or not it
4	Do you see that?	4	produces cancer, not just ovarian cancer, not
5	A. That's correct.	5	just lung cancer, but any cancer.
6	Q. And what they actually state	6	And so I'm not sure that that
7	with regard to experimental evidence is that	7	responds to your question.
8	there is limited evidence in experimental	8	BY MS. BOCKUS:
9	animals for the carcinogenicity of talc not	9	Q. No. My question was: You
10	containing asbestos or asbestiform fibers.	10	state in your report that IARC found strong
11	Correct?	11	evidence in animals, and I want to know where
12	MS. O'DELL: Object to the	12	you believe that statement occurs in the IARC
13	form.	13	monograph, or do you know?
14	BY MS. BOCKUS:	14	MS. O'DELL: And if you need a
15	Q. Did I read it incorrectly?	15	minute to look, feel free to do that.
16	A. No, I just lost you for a	16	A. Well, I can say that it might
17	moment.	17	take me a while to look for it, but I can say
18	Q. It's one sentence. Go ahead	18	that that's the basic definition of Group 2B,
19	and take your time and read it.	19	is limited evidence in humans and compelling
20	A. Yes, I agree with that. They	20	evidence in animals or other
21	found that inhaled tale, which does not	21	BY MS. BOCKUS:
22	contain asbestos or asbestiform fibers, is	22	Q. Tell me where you're looking at
23	Group 3.	23	that definition of 2B.
24	Q. That wasn't my question. I'm	24	A. Let me see here.
	, ₁ ,		
	Page 291		Page 293
1	talking about experimental animals because	1	Q. We earlier marked the
2	that's what you state in your report that	2	Exhibit 21, I think.
3	IARC found strong evidence in animals, and	3	A. Well, I have this other
4	yet the part of IARC that I know of where		
	yet the part of TARC that I know of where	4	exhibit, which is the preamble from another
5	they're addressing the animal data with	5	exhibit, which is the preamble from another situation; it's Exhibit P-346, and
5 6		I	
	they're addressing the animal data with	5	situation; it's Exhibit P-346, and
6	they're addressing the animal data with regard to talc is what I handed you in	5 6	situation; it's Exhibit P-346, and Q. Well, let me just ask a
6 7	they're addressing the animal data with regard to talc is what I handed you in Section 6.2, and it states there's limited	5 6 7	situation; it's Exhibit P-346, and Q. Well, let me just ask a different question, rather than looking at
6 7 8	they're addressing the animal data with regard to talc is what I handed you in Section 6.2, and it states there's limited evidence, correct?	5 6 7 8	situation; it's Exhibit P-346, and Q. Well, let me just ask a different question, rather than looking at the preamble.
6 7 8 9 10 11	they're addressing the animal data with regard to talc is what I handed you in Section 6.2, and it states there's limited evidence, correct? MS. O'DELL: Objection.	5 6 7 8 9	situation; it's Exhibit P-346, and Q. Well, let me just ask a different question, rather than looking at the preamble. A. All right.
6 7 8 9 10	they're addressing the animal data with regard to talc is what I handed you in Section 6.2, and it states there's limited evidence, correct? MS. O'DELL: Objection. A. It states that there's limited	5 6 7 8 9 10	situation; it's Exhibit P-346, and Q. Well, let me just ask a different question, rather than looking at the preamble. A. All right. Q. Because that's kind of
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6 7 8 9 10 11 12 13	they're addressing the animal data with regard to talc is what I handed you in Section 6.2, and it states there's limited evidence, correct? MS. O'DELL: Objection. A. It states that there's limited evidence I need to find this section in the monograph. Just bear with me for a	5 6 7 8 9 10 11 12	situation; it's Exhibit P-346, and Q. Well, let me just ask a different question, rather than looking at the preamble. A. All right. Q. Because that's kind of overarching. A. It is.
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6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	they're addressing the animal data with regard to talc is what I handed you in Section 6.2, and it states there's limited evidence, correct? MS. O'DELL: Objection. A. It states that there's limited evidence I need to find this section in the monograph. Just bear with me for a moment. It's page 412? (Document review.) A. Okay. I seem to be missing that part of the monograph. MS. O'DELL: Do you have the 93 monograph? THE WITNESS: Where's the this is 100C, and this is 93. Okay. Here it is. All right. Okay. A. Okay. The entire monograph is	5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	situation; it's Exhibit P-346, and Q. Well, let me just ask a different question, rather than looking at the preamble. A. All right. Q. Because that's kind of overarching. A. It is. Q. To know what IARC found with regard to talc and the evidence in animal models, wouldn't it be more appropriate to look at what they actually said about talc in the animal studies? A. Yes. MS. O'DELL: Objection, form. A. I would agree that that's the case. BY MS. BOCKUS:

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	in on 1. only	·	·
	Page 294		Page 296
1	cancer-causing potential of talc in animal	1	misstates the evidence.
2	studies, correct?	2	A. I believe that was their
3	MS. O'DELL: Objection to form.	3	assumption.
4	A. Well well, it says on that	4	BY MS. BOCKUS:
5	page there's limited evidence in experimental	5	Q. Okay. The studies that you
6	animals, so I'll agree that at least in this	6	reference in support of the notion that
7	location it does not say strong evidence.	7	asbestos in that may or may not exist in
8	BY MS. BOCKUS:	8	body powder contributes to cause ovarian
9	Q. And without going through the	9	cancer, none of the studies that you cite to
10	entire monograph, you don't know where that	10	have referenced an application of a product
11	language came from, is that fair, that you	11	to the perineum of the women and girls study,
12	used in your report?	12	correct?
13	MS. O'DELL: Object. Excuse	13	MS. O'DELL: Object to the
14	me. Object to the form. I think he	14	form.
15	was pointing directing you to the	15	THE WITNESS: I have a I
16	preamble and you withdrew your	16	apologize greatly, but I lost the
17	question, but	17	track. Could you repeat that
18	MS. BOCKUS: Well, let me just	18	question.
	· · · · · · · · · · · · · · · · · · ·	1	•
19	ask a qualifying question.	19	MS. BOCKUS: That's totally
20	BY MS. BOCKUS:	20	understandable because it was a little
21	Q. Does the preamble in any way	21	bit convoluted.
22	address their findings with regards to talc?	22	MS. O'DELL: Do you mind if we
23	A. No, the preamble addresses the	23	get the realtime running again? We're
24	methodology that's used by the IARC agency in	24	just off track here.
	Page 295		Page 297
1	addressing all the substances that they	1	MS. BOCKUS: That's okay.
2	evaluate.	2	BY MS. BOCKUS:
3	Q. Okay.	3	Q. I'm looking on page 5. Do you
4	A. And that's usually where I pull	4	see on page 5 of your report, sir,
5	things like that.	5	paragraph (c)?
6	MS. O'DELL: Are you finished,	6	A. Yes.
7	Doctor?	7	Q. And there you cite one, two,
8	THE WITNESS: Unless I'm going	8	three, four, five, six, seven, eight, nine,
9	to continue to search for this.	9	10, 11, 12 studies, correct?
10	BY MS. BOCKUS:	10	A. Yes.
11	Q. I don't need for you to look in	11	Q. Do you speak Italian?
12	the preamble, because I'm really only	12	A. I can read it pretty well.
13	interested in their findings as to talc, not	13	Q. Is that what you did for the
14	their overarching methodology, that sort of	14	Bertolotti study?
15	thing.	15	A. The Bertolotti study. Yes, I
16	A. Okay. But it's important to	16	read most of it. I may have kibitzed with
17	point out that this particular monograph is	17	some of my colleagues about the meaning of a
18	an evaluation of the carcinogenicity of talc	18	few words.
19	that does not contain asbestos or asbestiform	19	Q. At any rate, all of these
20	fibers, so	20	studies have to do with heavy occupational
21	Q. Correct. Which was, from their	21	exposure to asbestos, correct?
22	view, the tale that was included in all of	22	MS. O'DELL: Object to the
23	the studies that they reviewed, correct?	23	form.
23	MS. O'DELL: Objection,	24	A. Yes.
Z#	ivis. O DELL. Objection,	44	Α. 105.

75 (Pages 294 to 297)

	Page 298		Page 300
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1	BY MS. BOCKUS:	1	microenvironment, and based on what we know
2	Q. And you don't have any	2	about the mechanism of action of talc as well
3	information how the dose of asbestos to which	3	and even asbestos, they're all similar, and
4	these women were exposed during their heavy	4	for that reason would be expected to be
5	occupational exposure compares to any	5	additive.
6	exposure to asbestos from the use of body	6	Q. But the study hasn't been done
7	powder, correct?	7	even in a petri dish, has it?
8	A. Well, I think these were not	8	MS. O'DELL: Object to the
9	all occupational exposures, but I do not have	9	form.
10	information regarding things like the route	10	A. I don't know if there's
11	of exposure, no.	11	something in progress or not, but that's the
12	Q. Do you have any information	12	kind of study that is currently being looked
13	regarding the dose?	13	at. Combined exposures is the sort of the
14	A. No, I don't.	14	hallmark of research these days in
15	Q. Do you have any information	15	toxicology.
16	that would compare the dose of asbestos to	16	BY MS. BOCKUS:
17	which the women in these studies were	17	Q. Do you know of anyone who's
18	exposed	18	looking at that question?
19	A. Well, in some of the studies	19	A. I don't.
20	Q. Wait, I haven't finished my	20	Q. Okay. Have any of the heavy
21	question.	21	metals that you have identified been
22	A. Sorry.	22	identified as carcinogenic to the ovary by
23	Q to any alleged dose of	23	IARC?
24	asbestos in body powder?	24	A. No.
	Page 299		Page 301
1	Can you make any comparison	1	Q. I want you to turn to page 7
2	whatsoever to the amount of asbestos to which	2	now, if you would, please, on other evidence
3	these women were exposed to any exposure by	3	And you've talked about this paragraph a fair
4	any woman who has used a Johnson & Johnson	4	amount already, and I don't want to repeat
5	body powder?	5	any of the prior questions.
6	MC OIDELL OL: 44 4		
	MS. O'DELL: Object to the	6	But I want to ask you about the
7	form.	6 7	But I want to ask you about the statement in that first sentence, where you
	form. A. I don't think I'm able to make		But I want to ask you about the statement in that first sentence, where you say that transport of talc-containing
7	form. A. I don't think I'm able to make that kind of comparison.	7 8 9	But I want to ask you about the statement in that first sentence, where you say that transport of talc-containing materials from the perineum to the upper
7 8 9 10	form. A. I don't think I'm able to make that kind of comparison. BY MS. BOCKUS:	7 8 9 10	But I want to ask you about the statement in that first sentence, where you say that transport of tale-containing materials from the perineum to the upper reproductive tract and body cavities has been
7 8 9 10 11	form. A. I don't think I'm able to make that kind of comparison. BY MS. BOCKUS: Q. Okay. There are ways to study	7 8 9 10 11	But I want to ask you about the statement in that first sentence, where you say that transport of talc-containing materials from the perineum to the upper reproductive tract and body cavities has been shown to occur with startling regularity.
7 8 9 10 11 12	form. A. I don't think I'm able to make that kind of comparison. BY MS. BOCKUS: Q. Okay. There are ways to study whether two toxins combined increase a risk	7 8 9 10 11 12	But I want to ask you about the statement in that first sentence, where you say that transport of talc-containing materials from the perineum to the upper reproductive tract and body cavities has been shown to occur with startling regularity. And I want to stop right there.
7 8 9 10 11 12	form. A. I don't think I'm able to make that kind of comparison. BY MS. BOCKUS: Q. Okay. There are ways to study whether two toxins combined increase a risk more than exposure to a single toxin, whether	7 8 9 10 11 12 13	But I want to ask you about the statement in that first sentence, where you say that transport of talc-containing materials from the perineum to the upper reproductive tract and body cavities has been shown to occur with startling regularity. And I want to stop right there. If I recall your testimony
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7 8 9 10 11 12 13 14 15 16 17 18	form. A. I don't think I'm able to make that kind of comparison. BY MS. BOCKUS: Q. Okay. There are ways to study whether two toxins combined increase a risk more than exposure to a single toxin, whether it whether one offsets the risk of one of the toxins or whether you add them together, even multiply them together, right? A. Yes. Q. Has any such study ever been done with regard to talc and the heavy metals	7 8 9 10 11 12 13 14 15 16 17 18	But I want to ask you about the statement in that first sentence, where you say that transport of talc-containing materials from the perineum to the upper reproductive tract and body cavities has been shown to occur with startling regularity. And I want to stop right there. If I recall your testimony correctly, none of these studies even look at the transport of talc-containing materials from the perineum to the upper reproductive tract; isn't that correct? MS. O'DELL: Object to the form.
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7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	form. A. I don't think I'm able to make that kind of comparison. BY MS. BOCKUS: Q. Okay. There are ways to study whether two toxins combined increase a risk more than exposure to a single toxin, whether it whether one offsets the risk of one of the toxins or whether you add them together, even multiply them together, right? A. Yes. Q. Has any such study ever been done with regard to talc and the heavy metals that you identify in your report? A. Not specifically a study to	7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	But I want to ask you about the statement in that first sentence, where you say that transport of talc-containing materials from the perineum to the upper reproductive tract and body cavities has beer shown to occur with startling regularity. And I want to stop right there. If I recall your testimony correctly, none of these studies even look at the transport of talc-containing materials from the perineum to the upper reproductive tract; isn't that correct? MS. O'DELL: Object to the form. A. Well, it is true that most of the research that's been done in this area
7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	form. A. I don't think I'm able to make that kind of comparison. BY MS. BOCKUS: Q. Okay. There are ways to study whether two toxins combined increase a risk more than exposure to a single toxin, whether it whether one offsets the risk of one of the toxins or whether you add them together, even multiply them together, right? A. Yes. Q. Has any such study ever been done with regard to talc and the heavy metals that you identify in your report? A. Not specifically a study to look at the combined contribution, but we	7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	But I want to ask you about the statement in that first sentence, where you say that transport of talc-containing materials from the perineum to the upper reproductive tract and body cavities has beer shown to occur with startling regularity. And I want to stop right there. If I recall your testimony correctly, none of these studies even look at the transport of talc-containing materials from the perineum to the upper reproductive tract; isn't that correct? MS. O'DELL: Object to the form. A. Well, it is true that most of the research that's been done in this area has been done on materials that have been
7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	form. A. I don't think I'm able to make that kind of comparison. BY MS. BOCKUS: Q. Okay. There are ways to study whether two toxins combined increase a risk more than exposure to a single toxin, whether it whether one offsets the risk of one of the toxins or whether you add them together, even multiply them together, right? A. Yes. Q. Has any such study ever been done with regard to talc and the heavy metals that you identify in your report? A. Not specifically a study to	7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	But I want to ask you about the statement in that first sentence, where you say that transport of talc-containing materials from the perineum to the upper reproductive tract and body cavities has been shown to occur with startling regularity. And I want to stop right there. If I recall your testimony correctly, none of these studies even look at the transport of talc-containing materials from the perineum to the upper reproductive tract; isn't that correct? MS. O'DELL: Object to the form. A. Well, it is true that most of the research that's been done in this area

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	AICH I. CHIP Co	1	
	Page 302		Page 304
1	application to the perineum is equivalent to	1	those studies that you list here done in
2	that.	2	women who were standing up?
3	Q. Do you have an opinion as to	3	A. The studies that I list in
4	what percentage of the talcum powder applied	4	other evidence?
5	in a daily dusting to the perineum makes its	5	Q. Yes.
6	way to the vagina?	6	A. I think not.
7	A. No, I don't know.	7	Q. In fact, were any of them done
8	Q. Do you have an opinion as to	8	in women who were inclined with their head
9	what percentage of the talc that, in your	9	elevated over their hips?
10	opinion, would make its way to the vagina	10	A. No.
11	would actually make its way to the cervix?	11	Q. So my question is: Where do
12	A. I don't know that either.	12	you get the term "startling regularity" with
13	Q. And out of the talc that makes	13	regard to the transport of talc from outside
14	its way to the cervix, what percentage makes	14	a woman's body to the upper reproductive
15	it past the cervix into the uterus?	15	tract?
16	A. That, I don't know either.	16	MS. O'DELL: Object to the
17	Q. Do you have any reason to	17	form.
18	believe that tale would migrate with more	18	A. The propensity of evidence of
19	frequency or rapidity than sperm?	19	rapid transport of particulate material
20	MS. O'DELL: Objection to form.	20	regarding regardless of its composition.
21	A. No, I don't have reason to	21	BY MS. BOCKUS:
22	believe that would be the case.	22	Q. Particulate material inserted
23	BY MS. BOCKUS:	23	•
23 24		24	well into a woman's vagina whose hips are
24	Q. Would you agree, in fact, that	24	above her head, correct?
	Page 303		Page 305
1	it is unlikely that talc, an inert particle,	1	MS. O'DELL: Objection to form.
2	would travel as quickly or in the same	2	A. Well, we have other studies
3	percentages as sperm through the reproductive	3	too. We have the powdered glove examination
4	tract?	4	studies, things of that nature, that are a
5	MS. O'DELL: Object to the	5	little bit different.
6	form.	6	BY MS. BOCKUS:
7	A. I think the transport time is	7	Q. And you believe they support
8	roughly the same for any particulate matter,	8	your conclusion that tale is transported from
9	including sperm.	9	the perineum to the upper reproductive tract
10	BY MS. BOCKUS:	10	with startling regularity?
11	Q. Do you have any studies to	11	A. I think that's a valid
12	support that opinion?	12	conclusion supported by the evidence, yes.
13	A. Well, we know we know the	13	Q. I'm turning to page 8 now, and
14	we know the velocity of motile sperm; it's	14	the number that you have here and you've
15	very slow. And we have studies that have	15	repeated it a couple of times today about
16	shown the progression of particles through	16	your opinion that the elimination of tale as
17	the fallopian tubes at at least that fast a	17	a risk could result in over 3,000 lives saved
18	rate, possibly faster.	18	in the U.S. each year.
19	And so the motility of sperm is	19	How did you come to that
20	slower than the rate at which it passes		•
∠ ∪	through the female reproductive system, so	20	conclusion?
	amough the temate reproductive system, so	21	A. Well, I'm referring to talcum
21		1 22	
21 22	there are obviously other mechanisms at play	22	powder here
21		22 23 24	powder here Q. Okay. Sure. A which is the complete

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	- 006		
	Page 306		Page 308
1	product.	1	A. There may not have been use of
2	I came to that conclusion based	2	talcum powder in all those women, that's
3	on the number of new cases of ovarian cancer	3	correct.
4	that are diagnosed in the United States each	4	Q. Do you have any notion as to
5	year and the number of ovarian cancer deaths	5	what percent of those women may have used
6	that occur each year.	6	talcum powder?
7	And essentially, of 21,000 or	7	A. Based on these various studies,
8	so cases of new cases of ovarian cancer,	8	it seems to vary between 30 and 60%. It's
9	there are corresponding 14,000 or more deaths	9	more so in the U.S., Australia and the U.K.
10	each year, so that's a two-thirds fatality	10	Q. Do you have an opinion as to
11	rate if you look over time.	11	how regularly a women needs to use talcum
12	The at 30% increase in the	12	powder before her risk of ovarian cancer is
13	risk of or a 30% increase in the risk of	13	increased by 30%?
14	cancer applied in reverse, that is reducing	14	A. Well, based on the epidemiology
15	those that 30% increased risk from the use	15	studies, that risk occurs in the population
16	of perineal application of talcum powder	16	in general from ever use as opposed to never
17	could result in the prevention of as many as	17	use, and so it would depend on the individual
18	3,000 lives, depending on the prevalence of	18	woman.
19	use.	19	Each person has an individual
20	Q. Would that calculation require	20	susceptibility and individual characteristics
21	that 100% of the women in the U.S. be using	21	and would probably have an individual use
22	talcum powder on a daily basis?	22	pattern. So I couldn't say for any
23	A. It would require a hundred	23	individual woman.
24	percent of the women in the U.S. to stop	24	Q. And that's not what I'm asking
	F		Q. 1 210 1200 1201 Water 1 21 Water 1
	Page 307		Page 309
1	using talcum powder on a daily basis.	1	for. I'm really asking for in general,
2	Q. That wasn't my question.	2	because that's what epidemiology is, correct?
3	In order to attribute	3	It's not talking about an individual woman,
4	A. Well, my answer to your	4	right?
5	question then is no.	5	A. That's correct, it's describing
6	Q. In order to attribute 30% of	6	it in the population.
7	all ovarian cancer deaths to the use of	7	Q. So in the population, in the
8	talcum powder let me back up.	8	studies that you've reviewed, what is the
9	The data that you have that	9	minimum number of days per month, or however
10	you've cited is talking about the percentage	10	you want to describe it, that a woman would
10 11		10 11	you want to describe it, that a woman would need to use talcum powder before she would be
	of women the percentage of women who use		
11		11	need to use talcum powder before she would be
11 12 13	of women the percentage of women who use talcum powder who are diagnosed with ovarian cancer, correct?	11 12	need to use talcum powder before she would be included in the group that you believe have a 30% increased risk of ovarian cancer?
11 12	of women the percentage of women who use talcum powder who are diagnosed with ovarian	11 12 13	need to use talcum powder before she would be included in the group that you believe have a
11 12 13 14 15	of women the percentage of women who use talcum powder who are diagnosed with ovarian cancer, correct? MS. O'DELL: Object to the form.	11 12 13 14	need to use talcum powder before she would be included in the group that you believe have a 30% increased risk of ovarian cancer? MS. O'DELL: Object to the form.
11 12 13 14	of women the percentage of women who use talcum powder who are diagnosed with ovarian cancer, correct? MS. O'DELL: Object to the form. A. It is the total number of new	11 12 13 14 15	need to use talcum powder before she would be included in the group that you believe have a 30% increased risk of ovarian cancer? MS. O'DELL: Object to the form. A. The only qualifier that I've
11 12 13 14 15 16	of women the percentage of women who use talcum powder who are diagnosed with ovarian cancer, correct? MS. O'DELL: Object to the form. A. It is the total number of new diagnoses per year.	11 12 13 14 15 16	need to use talcum powder before she would be included in the group that you believe have a 30% increased risk of ovarian cancer? MS. O'DELL: Object to the form. A. The only qualifier that I've been able to come up with and that I've used
11 12 13 14 15 16 17	of women the percentage of women who use talcum powder who are diagnosed with ovarian cancer, correct? MS. O'DELL: Object to the form. A. It is the total number of new diagnoses per year. BY MS. BOCKUS:	11 12 13 14 15 16 17	need to use talcum powder before she would be included in the group that you believe have a 30% increased risk of ovarian cancer? MS. O'DELL: Object to the form. A. The only qualifier that I've been able to come up with and that I've used in this report is the regular use of talcum
11 12 13 14 15 16 17 18	of women the percentage of women who use talcum powder who are diagnosed with ovarian cancer, correct? MS. O'DELL: Object to the form. A. It is the total number of new diagnoses per year. BY MS. BOCKUS: Q. Okay.	11 12 13 14 15 16 17 18	need to use talcum powder before she would be included in the group that you believe have a 30% increased risk of ovarian cancer? MS. O'DELL: Object to the form. A. The only qualifier that I've been able to come up with and that I've used
11 12 13 14 15 16 17 18 19 20	of women the percentage of women who use talcum powder who are diagnosed with ovarian cancer, correct? MS. O'DELL: Object to the form. A. It is the total number of new diagnoses per year. BY MS. BOCKUS: Q. Okay. A. I think last year was	11 12 13 14 15 16 17 18	need to use talcum powder before she would be included in the group that you believe have a 30% increased risk of ovarian cancer? MS. O'DELL: Object to the form. A. The only qualifier that I've been able to come up with and that I've used in this report is the regular use of talcum powder. BY MS. BOCKUS:
11 12 13 14 15 16 17 18 19 20 21	of women the percentage of women who use talcum powder who are diagnosed with ovarian cancer, correct? MS. O'DELL: Object to the form. A. It is the total number of new diagnoses per year. BY MS. BOCKUS: Q. Okay. A. I think last year was 22,000-something.	11 12 13 14 15 16 17 18 19 20 21	need to use talcum powder before she would be included in the group that you believe have a 30% increased risk of ovarian cancer? MS. O'DELL: Object to the form. A. The only qualifier that I've been able to come up with and that I've used in this report is the regular use of talcum powder. BY MS. BOCKUS: Q. Okay.
11 12 13 14 15 16 17 18 19 20	of women the percentage of women who use talcum powder who are diagnosed with ovarian cancer, correct? MS. O'DELL: Object to the form. A. It is the total number of new diagnoses per year. BY MS. BOCKUS: Q. Okay. A. I think last year was 22,000-something. Q. But that number, 22,000, 100%	11 12 13 14 15 16 17 18 19 20 21 22	need to use talcum powder before she would be included in the group that you believe have a 30% increased risk of ovarian cancer? MS. O'DELL: Object to the form. A. The only qualifier that I've been able to come up with and that I've used in this report is the regular use of talcum powder. BY MS. BOCKUS: Q. Okay. A. And that is going to vary over
11 12 13 14 15 16 17 18 19 20 21	of women the percentage of women who use talcum powder who are diagnosed with ovarian cancer, correct? MS. O'DELL: Object to the form. A. It is the total number of new diagnoses per year. BY MS. BOCKUS: Q. Okay. A. I think last year was 22,000-something.	11 12 13 14 15 16 17 18 19 20 21	need to use talcum powder before she would be included in the group that you believe have a 30% increased risk of ovarian cancer? MS. O'DELL: Object to the form. A. The only qualifier that I've been able to come up with and that I've used in this report is the regular use of talcum powder. BY MS. BOCKUS: Q. Okay.

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	D 210	1	D 210
	Page 310		Page 312
1	regular use.	1	no threshold of exposure for risk; that we
2	Q. And over how many years must a	2	are we are right to use a zero threshold
3	woman use talcum powder on a regular basis	3	approach until we know more about the
4	before her risk of ovarian cancer is	4	possibility of a threshold below which
5	increased to 30%	5	exposure would be safe. At the current time
6	MS. O'DELL: Object to the	6	we don't have that information.
7	form.	7	Q. Do you believe that there
8	BY MS. BOCKUS:	8	probably is a threshold below which use is
9	Q in your opinion?	9	safe?
10	MS. BOCKUS: Sorry.	10	A. In the carcinogenic process,
11	A. Some of the studies have	11	which we haven't really talked about in this
12	focused on usage periods as short as one	12	session today, there is an insult to a cell
13	year, but most have studied longer periods of	13	which affects the genetic material, the DNA.
14	use and separated use into things like	14	And there are built-in repair mechanisms that
15	decades or accumulated total person-years	15	the cell has for fixing that problem that
16	based on reports of the women, multiplying	16	occurred, a mutation, for example.
17	frequency by time.	17	These kinds of insults are
18	So again, it would depend on	18	happening to cells all the time, not just
19	the individual, but the research reports	19	from carcinogens in our environment, but just
20	hover around five to ten years of regular	20	from natural occurrences, even endogenous
21	use, resulting in significant odds ratios.	21	biochemical reactions cause these problems.
22	BY MS. BOCKUS:	22	The question is: Is the repair
23	Q. As I understand it in	23	process sufficient to undo what's been done?
24	toxicology, one of the basic tenets is that	24	And an exposure to environmental carcinogens,
	Page 311		Page 313
1	it's the dose that makes the poison, correct?	1	that repair process is often overwhelmed so
2	A. That's correct.	2	that it cannot catch up with the damage
3	Q. That water can kill you if you	3	that's being created, and a tumor is born,
4	drink too much of it, right?	4	basically.
5	A. Theoretically.	5	That is where the concept of
6	Q. In a short period of time.	6	threshold comes from. Have we overwhelmed
7	And so I'm trying to find out	7	the repair or not, and we don't have enough
8	what you have determined is the threshold of	8	research evidence or scientific evidence to
9	risk is for talcum powder use by women.	9	be able to define that line at this point.
10	Do you have an opinion as to at what point a	10	Q. Has there ever been a study
11	threshold has been reached where the use of	11	that showed that talcum powder caused DNA
12	talcum powder by women in their perineal	12	damage in normal ovarian epithelial tissue?
13	region increases their risk?	13	A. Well, we do have the studies
14	A. I think any use of carcinogenic	14	that have recently been produced by Fletcher
15	materials or any exposure to carcinogenic	15	and Saed that show the inflammatory process
16	materials increases the risk somewhat. A	16	is influenced by tale, and this is nonfibrous
		17	talc, that result in mutagenic events that
17	greater exposure, based on the		
	<u> </u>	18	are available for promotion, and there are
17	"dose makes the poison" principle, would	18 19	are available for promotion, and there are biomarkers that have also been established
17 18 19	"dose makes the poison" principle, would result in a greater risk.		<u>-</u>
17 18 19 20	"dose makes the poison" principle, would result in a greater risk. And we know from toxicologic	19	biomarkers that have also been established for that.
17 18 19 20 21	"dose makes the poison" principle, would result in a greater risk. And we know from toxicologic studies that intense exposures can sometimes	19 20	biomarkers that have also been established for that. Q. The studies by Saed did not
17 18 19 20 21 22	"dose makes the poison" principle, would result in a greater risk. And we know from toxicologic studies that intense exposures can sometimes accelerate the process and even shorten the	19 20 21	biomarkers that have also been established for that. Q. The studies by Saed did not demonstrate DNA mutation, did they?
17 18 19 20 21	"dose makes the poison" principle, would result in a greater risk. And we know from toxicologic studies that intense exposures can sometimes	19 20 21 22	biomarkers that have also been established for that. Q. The studies by Saed did not

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	Page 314		Page 316
1	A. I think they actually did.	1	THE WITNESS: I'm sorry, it
2	BY MS. BOCKUS:	2	appears that I do need to get the
3		3	original paper here. There it is.
4	Q. That's your reading of them? A. Yes.	4	
			Okay. Thank you.
5	Q. What Saed did is he placed talc	5	(Document review.)
6	on cultured ovarian cancer cells, correct?	6	BY MS. BOCKUS:
7	A. Yes.	7	Q. Can you answer the question:
8	Q. And that actually what he	8	Did Saed have any either positive or negative
9	recorded was an elevation in the CA-125?	9	controls that he used in his experiments?
10	A. That's one of the things he	10	MS. O'DELL: Object to the
11	did. He also measured he did a number of	11	form.
12	genetic studies. He did transcribed RNA. He	12	A. I think he did, but I'd like to
13	located individual SNPs, which are single	13	actually find it in here so I can give you
14	nucleotide polymorphisms, in the genetic	14	the specifics.
15	material.	15	Well, he used normal cells and
16	And he found that as a result	16	epithelial ovarian cancer cells, and one was
17	of that treatment, those mutations altered	17	the control for the other. He treated them
18	the effectiveness of antioxidant enzymes that	18	in the same way.
19	are part of the protection mechanism and	19	BY MS. BOCKUS:
20	shield the repair process of the cell from	20	Q. Let me ask a different
21	further damage.	21	question.
22	Q. Let's go back to the CA-125.	22	What I'm asking is: Did he
23	MS. O'DELL: If you need to	23	use, say, glass beads to see if as a
24	pull the paper out, Doctor, just, if	24	control to the talc? Did he have anything
	Page 315		Page 317
1	you want to take a moment and do that.	1	that he was controlling the cells' reaction
2	I know you were searching for it while	2	to against the talc?
3	you were talking.	3	A. I don't believe so.
4	THE WITNESS: Yes, I think I	4	Q. That would be important in an
5	have it right here.	5	experiment of this nature, would you not
6	MS. BOCKUS: These are just	6	agree with that?
7	general questions that I'm going to	7	MS. O'DELL: Object to the
8	ask you.	8	form.
9	MS. O'DELL: You still may get	9	A. Well, he did utilize normal and
10	the paper out.	10	cancerous cells, which would theoretically
11	MS. BOCKUS: Do whatever you	11	act as a control in that experiment.
12	want to do.	12	BY MS. BOCKUS:
		13	Q. That's not my question. I'm
13	THE WITNESS: You can go ahead.	1 13	Q. That's not my question. Thi
13 14	I'm	14	
	•		really asking about another element that he
14	I'm	14	really asking about another element that he is exposing the cells to, both the normal and
14 15	I'm BY MS. BOCKUS: Q. What controls did Saed use?	14 15	really asking about another element that he is exposing the cells to, both the normal and the cancerous cells.
14 15 16 17	I'm BY MS. BOCKUS: Q. What controls did Saed use? Did he use any controls? In other words, did	14 15 16	really asking about another element that he is exposing the cells to, both the normal and the cancerous cells. MS. O'DELL: Objection to form.
14 15 16 17 18	I'm BY MS. BOCKUS: Q. What controls did Saed use? Did he use any controls? In other words, did he place a known foreign object that was	14 15 16 17 18	really asking about another element that he is exposing the cells to, both the normal and the cancerous cells. MS. O'DELL: Objection to form. BY MS. BOCKUS:
14 15 16 17 18 19	I'm BY MS. BOCKUS: Q. What controls did Saed use? Did he use any controls? In other words, did he place a known foreign object that was not that was known not to be a carcinogen	14 15 16 17 18 19	really asking about another element that he is exposing the cells to, both the normal and the cancerous cells. MS. O'DELL: Objection to form. BY MS. BOCKUS: Q. To see if the reaction was just
14 15 16 17 18 19 20	I'm BY MS. BOCKUS: Q. What controls did Saed use? Did he use any controls? In other words, did he place a known foreign object that was not that was known not to be a carcinogen on the cultured ovarian cells to see if there	14 15 16 17 18 19 20	really asking about another element that he is exposing the cells to, both the normal and the cancerous cells. MS. O'DELL: Objection to form. BY MS. BOCKUS: Q. To see if the reaction was just a reaction to a foreign body versus talc
14 15 16 17 18 19 20 21	I'm BY MS. BOCKUS: Q. What controls did Saed use? Did he use any controls? In other words, did he place a known foreign object that was not that was known not to be a carcinogen on the cultured ovarian cells to see if there was a difference?	14 15 16 17 18 19 20 21	really asking about another element that he is exposing the cells to, both the normal and the cancerous cells. MS. O'DELL: Objection to form. BY MS. BOCKUS: Q. To see if the reaction was just a reaction to a foreign body versus talc specifically.
14 15 16 17 18 19 20 21	I'm BY MS. BOCKUS: Q. What controls did Saed use? Did he use any controls? In other words, did he place a known foreign object that was not that was known not to be a carcinogen on the cultured ovarian cells to see if there was a difference? MS. O'DELL: Can you just pause	14 15 16 17 18 19 20 21 22	really asking about another element that he is exposing the cells to, both the normal and the cancerous cells. MS. O'DELL: Objection to form. BY MS. BOCKUS: Q. To see if the reaction was just a reaction to a foreign body versus talc specifically. Did he do that?
14 15 16 17 18 19 20 21	I'm BY MS. BOCKUS: Q. What controls did Saed use? Did he use any controls? In other words, did he place a known foreign object that was not that was known not to be a carcinogen on the cultured ovarian cells to see if there was a difference?	14 15 16 17 18 19 20 21	really asking about another element that he is exposing the cells to, both the normal and the cancerous cells. MS. O'DELL: Objection to form. BY MS. BOCKUS: Q. To see if the reaction was just a reaction to a foreign body versus talc specifically.

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	Page 318		Page 320
1	A. I don't believe that he	1	A. I don't specifically know.
2	provided a control exposure as part of this	2	BY MS. BOCKUS:
3	experiment.	3	Q. There's no way to know that, is
4	BY MS. BOCKUS:	4	there?
5	Q. And you would agree that there	5	A. No, there's not.
6	are many things that will increase a CA-125,	6	Q. Let me find my there we go.
7	correct?	7	The Saed paper that you were
8	MS. O'DELL: Object to the	8	looking at just a minute ago, it has
9	form.	9	something printed across it. What does that
10	A. Yes, it's an acute-phase	10	say?
11	reactant.	11	A. In blue here?
12	BY MS. BOCKUS:	12	Q. Uh-huh.
13	Q. Pregnancy can increase	13	A. "For Peer Review."
14	somebody's CA-125?	14	Q. Okay. So it hasn't yet been
15	A. That's correct.	15	peer reviewed; is that correct?
16	Q. And with regard to the SNPs,	16	MS. O'DELL: Object to the
17	that is not the same thing as a test showing	17	form.
18	mutation, correct?	18	A. It's been submitted.
19	MS. O'DELL: Object to the	19	BY MS. BOCKUS:
20	form.	20	Q. So does that mean it has not
21	BY MS. BOCKUS:	21	yet been peer reviewed?
22	Q. It's a surrogate.	22	MS. O'DELL: Object to the
23	A. Well, it's because there was	23	form.
24	transcribed RNA that was used to determine	24	A. I think it's been accepted for
	Page 319		Page 321
1	their presence, and the it's just part of	1	publication.
2	their procedure, but it identifies genetic	2	BY MS. BOCKUS:
3	alterations. And those genetic alterations	3	O D-+ 41 1
1		ا ا	Q. But the copy you have says on
4	transformed into differential enzyme	4	it "For Peer Review," correct?
4 5	transformed into differential enzyme activities.		
		4	it "For Peer Review," correct?
5	activities.	4 5	it "For Peer Review," correct? A. That's correct.
5 6	activities. Q. Do you know whether there are standard tests for genotoxicity and mutagenicity?	4 5 6	it "For Peer Review," correct? A. That's correct. Q. In the paragraph that we were looking at earlier, where you were talking about the startling regularity, later on in
5 6 7	activities. Q. Do you know whether there are standard tests for genotoxicity and	4 5 6 7	it "For Peer Review," correct? A. That's correct. Q. In the paragraph that we were looking at earlier, where you were talking about the startling regularity, later on in the paragraph you state that there
5 6 7 8 9 10	activities. Q. Do you know whether there are standard tests for genotoxicity and mutagenicity? A. There are lots of standard tests, yes.	4 5 6 7 8 9	it "For Peer Review," correct? A. That's correct. Q. In the paragraph that we were looking at earlier, where you were talking about the startling regularity, later on in the paragraph you state that there is clearly sufficient particulate
5 6 7 8 9 10 11	activities. Q. Do you know whether there are standard tests for genotoxicity and mutagenicity? A. There are lots of standard tests, yes. Q. And Saed didn't use any of	4 5 6 7 8 9 10 11	it "For Peer Review," correct? A. That's correct. Q. In the paragraph that we were looking at earlier, where you were talking about the startling regularity, later on in the paragraph you state that there is clearly sufficient particulate materials applied routinely to the perineum
5 6 7 8 9 10 11	activities. Q. Do you know whether there are standard tests for genotoxicity and mutagenicity? A. There are lots of standard tests, yes. Q. And Saed didn't use any of those, did he?	4 5 6 7 8 9 10 11	it "For Peer Review," correct? A. That's correct. Q. In the paragraph that we were looking at earlier, where you were talking about the startling regularity, later on in the paragraph you state that there is clearly sufficient particulate materials applied routinely to the perineum have ready access and in sufficient
5 6 7 8 9 10 11 12 13	activities. Q. Do you know whether there are standard tests for genotoxicity and mutagenicity? A. There are lots of standard tests, yes. Q. And Saed didn't use any of those, did he? MS. O'DELL: Object to the	4 5 6 7 8 9 10 11 12 13	it "For Peer Review," correct? A. That's correct. Q. In the paragraph that we were looking at earlier, where you were talking about the startling regularity, later on in the paragraph you state that there is clearly sufficient particulate materials applied routinely to the perineum have ready access and in sufficient quantities to produce biologic responses in
5 6 7 8 9 10 11 12 13	activities. Q. Do you know whether there are standard tests for genotoxicity and mutagenicity? A. There are lots of standard tests, yes. Q. And Saed didn't use any of those, did he? MS. O'DELL: Object to the form.	4 5 6 7 8 9 10 11 12 13	it "For Peer Review," correct? A. That's correct. Q. In the paragraph that we were looking at earlier, where you were talking about the startling regularity, later on in the paragraph you state that there is clearly sufficient particulate materials applied routinely to the perineum have ready access and in sufficient quantities to produce biologic responses in internal tissues.
5 6 7 8 9 10 11 12 13 14	activities. Q. Do you know whether there are standard tests for genotoxicity and mutagenicity? A. There are lots of standard tests, yes. Q. And Saed didn't use any of those, did he? MS. O'DELL: Object to the form. A. Well, he went directly to cells	4 5 6 7 8 9 10 11 12 13 14	it "For Peer Review," correct? A. That's correct. Q. In the paragraph that we were looking at earlier, where you were talking about the startling regularity, later on in the paragraph you state that there is clearly sufficient particulate materials applied routinely to the perineum have ready access and in sufficient quantities to produce biologic responses in internal tissues. What internal tissues have you
5 6 7 8 9 10 11 12 13 14 15	activities. Q. Do you know whether there are standard tests for genotoxicity and mutagenicity? A. There are lots of standard tests, yes. Q. And Saed didn't use any of those, did he? MS. O'DELL: Object to the form. A. Well, he went directly to cells in culture to see what happened when they	4 5 6 7 8 9 10 11 12 13 14 15	it "For Peer Review," correct? A. That's correct. Q. In the paragraph that we were looking at earlier, where you were talking about the startling regularity, later on in the paragraph you state that there is clearly sufficient particulate materials applied routinely to the perineum have ready access and in sufficient quantities to produce biologic responses in internal tissues. What internal tissues have you seen any study recording a biologic response
5 6 7 8 9 10 11 12 13 14 15 16	activities. Q. Do you know whether there are standard tests for genotoxicity and mutagenicity? A. There are lots of standard tests, yes. Q. And Saed didn't use any of those, did he? MS. O'DELL: Object to the form. A. Well, he went directly to cells in culture to see what happened when they were treated with talc.	4 5 6 7 8 9 10 11 12 13 14 15 16 17	it "For Peer Review," correct? A. That's correct. Q. In the paragraph that we were looking at earlier, where you were talking about the startling regularity, later on in the paragraph you state that there is clearly sufficient particulate materials applied routinely to the perineum have ready access and in sufficient quantities to produce biologic responses in internal tissues. What internal tissues have you seen any study recording a biologic response to talc from?
5 6 7 8 9 10 11 12 13 14 15 16 17	activities. Q. Do you know whether there are standard tests for genotoxicity and mutagenicity? A. There are lots of standard tests, yes. Q. And Saed didn't use any of those, did he? MS. O'DELL: Object to the form. A. Well, he went directly to cells in culture to see what happened when they were treated with talc. BY MS. BOCKUS:	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	it "For Peer Review," correct? A. That's correct. Q. In the paragraph that we were looking at earlier, where you were talking about the startling regularity, later on in the paragraph you state that there is clearly sufficient particulate materials applied routinely to the perineum have ready access and in sufficient quantities to produce biologic responses in internal tissues. What internal tissues have you seen any study recording a biologic response to talc from? That was such a bad question,
5 6 7 8 9 10 11 12 13 14 15 16 17 18	activities. Q. Do you know whether there are standard tests for genotoxicity and mutagenicity? A. There are lots of standard tests, yes. Q. And Saed didn't use any of those, did he? MS. O'DELL: Object to the form. A. Well, he went directly to cells in culture to see what happened when they were treated with talc. BY MS. BOCKUS: Q. Does the amount of talc that	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	it "For Peer Review," correct? A. That's correct. Q. In the paragraph that we were looking at earlier, where you were talking about the startling regularity, later on in the paragraph you state that there is clearly sufficient particulate materials applied routinely to the perineum have ready access and in sufficient quantities to produce biologic responses in internal tissues. What internal tissues have you seen any study recording a biologic response to talc from? That was such a bad question, I'm going to ask it again.
5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	activities. Q. Do you know whether there are standard tests for genotoxicity and mutagenicity? A. There are lots of standard tests, yes. Q. And Saed didn't use any of those, did he? MS. O'DELL: Object to the form. A. Well, he went directly to cells in culture to see what happened when they were treated with talc. BY MS. BOCKUS: Q. Does the amount of talc that Saed used compare in any way to the amount of	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	it "For Peer Review," correct? A. That's correct. Q. In the paragraph that we were looking at earlier, where you were talking about the startling regularity, later on in the paragraph you state that there is clearly sufficient particulate materials applied routinely to the perineum have ready access and in sufficient quantities to produce biologic responses in internal tissues. What internal tissues have you seen any study recording a biologic response to talc from? That was such a bad question, I'm going to ask it again. What internal tissues are you
5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	activities. Q. Do you know whether there are standard tests for genotoxicity and mutagenicity? A. There are lots of standard tests, yes. Q. And Saed didn't use any of those, did he? MS. O'DELL: Object to the form. A. Well, he went directly to cells in culture to see what happened when they were treated with talc. BY MS. BOCKUS: Q. Does the amount of talc that Saed used compare in any way to the amount of talc that may reach a woman's ovary from	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	it "For Peer Review," correct? A. That's correct. Q. In the paragraph that we were looking at earlier, where you were talking about the startling regularity, later on in the paragraph you state that there is clearly sufficient particulate materials applied routinely to the perineum have ready access and in sufficient quantities to produce biologic responses in internal tissues. What internal tissues have you seen any study recording a biologic response to talc from? That was such a bad question, I'm going to ask it again. What internal tissues are you referring to there?
5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	activities. Q. Do you know whether there are standard tests for genotoxicity and mutagenicity? A. There are lots of standard tests, yes. Q. And Saed didn't use any of those, did he? MS. O'DELL: Object to the form. A. Well, he went directly to cells in culture to see what happened when they were treated with talc. BY MS. BOCKUS: Q. Does the amount of talc that Saed used compare in any way to the amount of talc that may reach a woman's ovary from perineal application?	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	it "For Peer Review," correct? A. That's correct. Q. In the paragraph that we were looking at earlier, where you were talking about the startling regularity, later on in the paragraph you state that there is clearly sufficient particulate materials applied routinely to the perineum have ready access and in sufficient quantities to produce biologic responses in internal tissues. What internal tissues have you seen any study recording a biologic response to talc from? That was such a bad question, I'm going to ask it again. What internal tissues are you referring to there? A. Well, it says including
5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	activities. Q. Do you know whether there are standard tests for genotoxicity and mutagenicity? A. There are lots of standard tests, yes. Q. And Saed didn't use any of those, did he? MS. O'DELL: Object to the form. A. Well, he went directly to cells in culture to see what happened when they were treated with talc. BY MS. BOCKUS: Q. Does the amount of talc that Saed used compare in any way to the amount of talc that may reach a woman's ovary from	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	it "For Peer Review," correct? A. That's correct. Q. In the paragraph that we were looking at earlier, where you were talking about the startling regularity, later on in the paragraph you state that there is clearly sufficient particulate materials applied routinely to the perineum have ready access and in sufficient quantities to produce biologic responses in internal tissues. What internal tissues have you seen any study recording a biologic response to talc from? That was such a bad question, I'm going to ask it again. What internal tissues are you referring to there?

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	Page 322		Page 324
1	the fallopian fimbriae and the epithelium of	1	fallopian tube goes into that fluid and just
2	the cavity.	2	gets moved around all the time; is that
3	Q. So and I know we've been	3	correct?
4	through this already, but to your knowledge,	4	MS. O'DELL: Objection. Excuse
5	there are no studies reporting biologic	5	me. Objection, form.
6	responses to talc in the vagina, correct?	6	A. Well, there's a fairly direct
7	A. Not that I'm aware.	7	presentation of the ovary, so there's not a
8	Q. You're not aware of any studies	8	large space there, but there is a space. And
9	reporting biologic responses to talc in the	9	whatever goes into that space remains there.
10	cervix, correct?	10	Some of it may come back out.
11	A. Correct.	11	BY MS. BOCKUS:
12	Q. Are you aware of any studies	12	Q. Does the fallopian tube move
13	reporting biologic response to the uterus?	13	around during the month?
14	A. No.	14	MS. O'DELL: Object to the
15	Q. Are you aware of any studies	15	form.
16	reporting a biologic response in the	16	A. I don't know.
17	fallopian tubes?	17	MS. BOCKUS: I'm almost
18	MS. O'DELL: Object to the	18	finished. I'm going through all the
19	form.	19	things that I've crossed off.
20	A. Well, I don't I'm not aware	20	BY MS. BOCKUS:
21	of studies that draws a direct correlation	21	Q. So I understand you correctly,
22	between exposure to talc and reaction in the	22	you have not identified a nonthreshold dose
23	fallopian tubes.	23	of tale; is that correct?
24	///	24	MS. O'DELL: Object to the
	Page 323		Page 325
1	BY MS. BOCKUS:	1	form.
2	Q. Okay. Is the ovary attached to	2	A. You mean a dose that is below a
3	the fallopian tube?	3	safe threshold?
4	A. It is it's in the proximity.	4	BY MS. BOCKUS:
5	It's not directly attached.	5	Q. Correct.
6	Q. And what surrounds the ovary?	6	
		0	A. No, I have not.
7	A. There's a structure that the	7	A. No, I have not.Q. Did you make any attempt to
7 8	A. There's a structure that the ovary itself?		
8 9	ovary itself? Q. Yes.	7 8 9	Q. Did you make any attempt to
8 9 10	ovary itself? Q. Yes. A. There's an epithelial membrane	7 8 9 10	Q. Did you make any attempt to extrapolate a de minimis risk level? MS. O'DELL: Object to the form.
8 9 10 11	ovary itself? Q. Yes. A. There's an epithelial membrane around the ovary, and	7 8 9 10 11	 Q. Did you make any attempt to extrapolate a de minimis risk level? MS. O'DELL: Object to the form. A. I did not. It would be nice to
8 9 10 11 12	ovary itself? Q. Yes. A. There's an epithelial membrane around the ovary, and Q. And then what touches the	7 8 9 10 11 12	Q. Did you make any attempt to extrapolate a de minimis risk level? MS. O'DELL: Object to the form. A. I did not. It would be nice to be able to do that, considering that most of
8 9 10 11 12 13	ovary itself? Q. Yes. A. There's an epithelial membrane around the ovary, and Q. And then what touches the epithelial membrane?	7 8 9 10 11 12 13	Q. Did you make any attempt to extrapolate a de minimis risk level? MS. O'DELL: Object to the form. A. I did not. It would be nice to be able to do that, considering that most of us have had talcum powder exposures of one
8 9 10 11 12 13 14	ovary itself? Q. Yes. A. There's an epithelial membrane around the ovary, and Q. And then what touches the epithelial membrane? A. Well, the fimbriae of the	7 8 9 10 11 12 13	Q. Did you make any attempt to extrapolate a de minimis risk level? MS. O'DELL: Object to the form. A. I did not. It would be nice to be able to do that, considering that most of us have had talcum powder exposures of one sort or another during our lives. And it's
8 9 10 11 12 13 14 15	ovary itself? Q. Yes. A. There's an epithelial membrane around the ovary, and Q. And then what touches the epithelial membrane? A. Well, the fimbriae of the fallopian tubes surround that and the rest of	7 8 9 10 11 12 13 14 15	Q. Did you make any attempt to extrapolate a de minimis risk level? MS. O'DELL: Object to the form. A. I did not. It would be nice to be able to do that, considering that most of us have had talcum powder exposures of one sort or another during our lives. And it's something that seems to have been felt to be
8 9 10 11 12 13 14 15	ovary itself? Q. Yes. A. There's an epithelial membrane around the ovary, and Q. And then what touches the epithelial membrane? A. Well, the fimbriae of the fallopian tubes surround that and the rest of it is just sort of space.	7 8 9 10 11 12 13 14 15	Q. Did you make any attempt to extrapolate a de minimis risk level? MS. O'DELL: Object to the form. A. I did not. It would be nice to be able to do that, considering that most of us have had talcum powder exposures of one sort or another during our lives. And it's something that seems to have been felt to be very useful.
8 9 10 11 12 13 14 15 16	ovary itself? Q. Yes. A. There's an epithelial membrane around the ovary, and Q. And then what touches the epithelial membrane? A. Well, the fimbriae of the fallopian tubes surround that and the rest of it is just sort of space. Q. Space. Is the space filled	7 8 9 10 11 12 13 14 15 16 17	Q. Did you make any attempt to extrapolate a de minimis risk level? MS. O'DELL: Object to the form. A. I did not. It would be nice to be able to do that, considering that most of us have had talcum powder exposures of one sort or another during our lives. And it's something that seems to have been felt to be very useful. So it would be nice to be able
8 9 10 11 12 13 14 15 16 17	ovary itself? Q. Yes. A. There's an epithelial membrane around the ovary, and Q. And then what touches the epithelial membrane? A. Well, the fimbriae of the fallopian tubes surround that and the rest of it is just sort of space. Q. Space. Is the space filled with fluid?	7 8 9 10 11 12 13 14 15 16 17	Q. Did you make any attempt to extrapolate a de minimis risk level? MS. O'DELL: Object to the form. A. I did not. It would be nice to be able to do that, considering that most of us have had talcum powder exposures of one sort or another during our lives. And it's something that seems to have been felt to be very useful. So it would be nice to be able to do that exercise, but I haven't I have
8 9 10 11 12 13 14 15 16 17 18	ovary itself? Q. Yes. A. There's an epithelial membrane around the ovary, and Q. And then what touches the epithelial membrane? A. Well, the fimbriae of the fallopian tubes surround that and the rest of it is just sort of space. Q. Space. Is the space filled with fluid? A. It is.	7 8 9 10 11 12 13 14 15 16 17 18	Q. Did you make any attempt to extrapolate a de minimis risk level? MS. O'DELL: Object to the form. A. I did not. It would be nice to be able to do that, considering that most of us have had talcum powder exposures of one sort or another during our lives. And it's something that seems to have been felt to be very useful. So it would be nice to be able to do that exercise, but I haven't I have not been prevented presented with the
8 9 10 11 12 13 14 15 16 17 18 19 20	ovary itself? Q. Yes. A. There's an epithelial membrane around the ovary, and Q. And then what touches the epithelial membrane? A. Well, the fimbriae of the fallopian tubes surround that and the rest of it is just sort of space. Q. Space. Is the space filled with fluid? A. It is. Q. And is that fluid kind of	7 8 9 10 11 12 13 14 15 16 17 18 19 20	Q. Did you make any attempt to extrapolate a de minimis risk level? MS. O'DELL: Object to the form. A. I did not. It would be nice to be able to do that, considering that most of us have had talcum powder exposures of one sort or another during our lives. And it's something that seems to have been felt to be very useful. So it would be nice to be able to do that exercise, but I haven't I have not been prevented presented with the information to approach that, nor am I aware
8 9 10 11 12 13 14 15 16 17 18 19 20 21	ovary itself? Q. Yes. A. There's an epithelial membrane around the ovary, and Q. And then what touches the epithelial membrane? A. Well, the fimbriae of the fallopian tubes surround that and the rest of it is just sort of space. Q. Space. Is the space filled with fluid? A. It is. Q. And is that fluid kind of moving around?	7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Q. Did you make any attempt to extrapolate a de minimis risk level? MS. O'DELL: Object to the form. A. I did not. It would be nice to be able to do that, considering that most of us have had talcum powder exposures of one sort or another during our lives. And it's something that seems to have been felt to be very useful. So it would be nice to be able to do that exercise, but I haven't I have not been prevented presented with the information to approach that, nor am I aware of anyone else who's been able to do it.
8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	ovary itself? Q. Yes. A. There's an epithelial membrane around the ovary, and Q. And then what touches the epithelial membrane? A. Well, the fimbriae of the fallopian tubes surround that and the rest of it is just sort of space. Q. Space. Is the space filled with fluid? A. It is. Q. And is that fluid kind of moving around? A. All the time.	7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q. Did you make any attempt to extrapolate a de minimis risk level? MS. O'DELL: Object to the form. A. I did not. It would be nice to be able to do that, considering that most of us have had talcum powder exposures of one sort or another during our lives. And it's something that seems to have been felt to be very useful. So it would be nice to be able to do that exercise, but I haven't I have not been prevented presented with the information to approach that, nor am I aware of anyone else who's been able to do it. BY MS. BOCKUS:
8 9 10 11 12 13 14 15 16 17 18 19 20 21	ovary itself? Q. Yes. A. There's an epithelial membrane around the ovary, and Q. And then what touches the epithelial membrane? A. Well, the fimbriae of the fallopian tubes surround that and the rest of it is just sort of space. Q. Space. Is the space filled with fluid? A. It is. Q. And is that fluid kind of moving around?	7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Q. Did you make any attempt to extrapolate a de minimis risk level? MS. O'DELL: Object to the form. A. I did not. It would be nice to be able to do that, considering that most of us have had talcum powder exposures of one sort or another during our lives. And it's something that seems to have been felt to be very useful. So it would be nice to be able to do that exercise, but I haven't I have not been prevented presented with the information to approach that, nor am I aware of anyone else who's been able to do it.

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A. Well, we'd need – we'd need don't have, to combine with the epidemiologic results. We need to define the mechanistic issues better than they are currently, and at that point I think we would be able to make some strong conclusions regular hasis are never diagnosed with ovarian anamer, correct? A. I think that's true. Q. And it's also true that the majority of women diagnosed with ovarian cancer correct? A. I think it's a majority, but there's a significant number who have. MS. OTFILI: Object to the form. A. I think it's a majority, but there's a significant number who have. BY MS. BOCKUS: Q. But the majority have not, correct? A. I twould say more than 50% have not. Q. And would you agree that — let me back up. When is the last time you conducted a pelvic exam? A. I see patients regularly, and in some cases, pelvic exams are either requised by the lists. Q. And you do not — what percentage of your patients are women? A. I robably half, maybe a little gard provided and pelving that and the precentage of your patients are women? A. Probably half, maybe a little gard provided and pelving that or contect of see the first of the patient to conducted a pelvic exams? A. I see patients regularly, and in some cases, pelvic exams are either requised or indicated by the issue. Q. And you do not — what percentage of your patients are women? A. Probably half, maybe a little gard provided p		Arch 1. Chip Co		, M.D., FII.D.
dose information, first of all, which we don't have, to combine with the epidemiologic results. We need to define the 6 mechanistic issues better than they are 6 currently, and at that point I think we would 8 be able to make some strong conclusions regarding potential thresholds of hazardous doses. Q. You would agree that the great majority of women who use talcum powder on a regular basis are never diagnosed with ovarian cancer, correct? A. I think that's true. Q. And it's also true that the 17 majority of women diagnosed with ovarian cancer have never used talcum powder on a regular basis, correct? MS. O'DELL: Object to the 20 mS. O'DELL: Object to the 21 form. A. I think it's a majority, but 22 ther's a significant number who have. BY MS. BOCKUS: Q. But the majority have not, correct? A. I have patients who are either workplace-related patients who have had chemical and that's true. I also save a number of environmental exposure patients that I see: And I also have a number of — required exams by regulation, either for licensure or certification. A. I think that's true. BY MS. O'DELL: Object to the 20 mS. O'DELL: Object to the 21 form. Page 327 BY MS. BOCKUS: Q. But the majority have not, correct? A. I think it's a majority have not, correct? A. I think it's a majority have not, or correct? A. I have patients wixe of evite manumber of patients for general required exams by regulation, either for licensure or certification. Page 327 BY MS. BOCKUS: Q. But the majority have not, or correct? A. I have patients wixe or department of the disease, and I go — I talk to them about the possibilities, and we look at ways of confirming that or refuting it, or in many conducted a pelvic exam? A. I haver the disease. Q. Under what circumstances did you do it two years ago? A. I see patients regularly, and in a couple of years. Q. Under what circumstances did you do it two years ago? A. I see patients dead or the patient dose understand that connection quite well, well and the patient dose under		Page 326		Page 328
don't have, to combine with the epidemiologic results. We need to define the mechanistic issues better than they are currently, and at that point I think we would be able to make some strong conclusions regarding potential thresholds of hazardous dose. Q. You would agree that the great majority of women who use talcum powder on a regular basis are never diagnosed with varian cancer, correct? A. I think that's true. Q. And it's also true that the great majority of women diagnosed with ovarian cancer have never used talcum powder on a regular basis, correct? M.S. O'DELL: Object to the form. A. I think it's a majority, but there's a significant number who have. Page 327 BY MS. BOCKUS: Q. But the majority have not, correct? A. I and I also true that the possibilities, and we look at ways of confirming that or refuting it, or in many Page 327 BY MS. BOCKUS: Q. But the majority have not, correct? A. I have primarily a referral practice in toxicology. A. I have primarily a referral toyout? A. I have primarily a referral practice in toxicology? A. I have primarily a referral toyout? A. I have primarily, and in types of patients who are either workplace-related patients who reciber workplace-related patients who read chemical or other substance exposures. I all shows a number of either workplace-related patients who have had chemical or other substance exposures. I all shows a number of either workplace-related patients who have a mumber of either workplace-related patients who have a mumber of either workplace-related patients who have a mumber of either workplace-related patients who have had chemical or other substance exposures. I all also see a number of patients who reciber workplace-related patients who have an unmber of everimental exposure patients who reveil have a mumber of everimental exposure patients who fave a number of everimental exposure patients who fave a number of everimental exposure patients that I see. A. I think that's true. Q. And so usent patients who they got the disease,	1	A. Well, we'd need we'd need	1	you? In other words, are they referred by
4 practice in toxicology. We need to define the 6 mechanistic issues better than they are currently, and at that point I think we would 8 be able to make some strong conclusions 9 regarding potential thresholds of hazardous 40 doses. 10 doses. 11 Q. You would agree that the great majority of women who use talcum powder on a regular basis are never diagnosed with 40 varian cancer, correct? 14 routine surveillance activities or required exams by regulation, either for licensure or certification. 15 dose 16 dose 17 dose 18 workplace-related patients who have had chemical or other substance exposures. I also have a number of environmental exposure patients that I see. 14 A. I think that's true. 15 dose ea number of patients for general routine surveillance activities or required exams by regulation, either for licensure or certification. 17 Q. Are you sent patients where the patient is trying to figure out why they got some disease? 18 dose 18 dose 19 dos	2		2	
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Q. How do patients come to see 24 innocent bystander, that they may get				
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83 (Pages 326 to 329)

	Page 330		Page 332
1	confused.	1	for that population of women?
2	Q. Have you ever been referred a	2	A. Well, it varies depending on
3	patient to determine why they have ovarian	3	the research study that has been done, but
4	cancer?	4	I've seen odds ratios or relative risks all
5	A. No.		the way from 1 or even below to very high
6		5 6	numbers, like 20 to 50.
	, ,		
7	accepted in the medical community for	7	Q. 20.0, is that what you're
8	determining why an individual woman has	8	saying?
9	developed ovarian cancer?	9	A. Yes, 20.0.
10	MS. O'DELL: Object to the	10	Q. Not 1.2, but 20.0?
11	form.	11	A. Correct.
12	A. Other than genetic testing that	12	Q. Okay.
13	identifies specific risks and history taking	13	A. Which is a which would be 20
14	that might identify other known risk factors	14	times the normal risk without the exposure.
15	for that woman, there is I don't believe	15	Q. Okay. So we've got obesity and
16	that there is any good or prescribed	16	heavy exposure to asbestos. Any other risk
17	procedure for making that determination, and	17	factors that you're familiar with?
18	there is no reasonable screening test that	18	MS. O'DELL: Objection
19	can find that cancer when it is at an early	19	excuse me. Objection, misstates the
20	stage.	20	doctor's testimony.
21	BY MS. BOCKUS:	21	You may answer.
22	Q. Do you believe that obesity	22	THE WITNESS: Okay.
23	causes ovarian cancer?	23	A. Other risk factors for ovarian
24	A. It certainly seems to be	24	cancer would include things like early
	Page 331		Page 333
1	related to the occurrence of ovarian cancer	1	menarche, late menopause, never being
2	from a statistical point of view.	2	pregnant. These are some of the more common
3	Q. What is the increase in a	3	risk factors that are identified.
4	woman's risk of ovarian cancer if she's obese	4	There are genetic risk factors
5			
	compared to a nonobese woman?	5	that are known, like the BRCA mutations,
6	A. In terms of numbers?	5 6	that are known, like the BRCA mutations, which confer an increased risk. Family
6 7	A. In terms of numbers?		which confer an increased risk. Family
	A. In terms of numbers? Q. Yes, sir.	6	which confer an increased risk. Family history.
7	A. In terms of numbers?Q. Yes, sir.A. I don't know the I don't	6 7	which confer an increased risk. Family history. BY MS. BOCKUS:
7 8	A. In terms of numbers? Q. Yes, sir. A. I don't know the I don't know the numbers.	6 7 8	which confer an increased risk. Family history. BY MS. BOCKUS: Q. Do you know the odds ratios of
7 8 9	A. In terms of numbers? Q. Yes, sir. A. I don't know the I don't know the numbers. Q. What other risk factors are you	6 7 8 9	which confer an increased risk. Family history. BY MS. BOCKUS: Q. Do you know the odds ratios of any of the risk factors that you just
7 8 9 10 11	A. In terms of numbers? Q. Yes, sir. A. I don't know the I don't know the numbers. Q. What other risk factors are you familiar with for ovarian cancer?	6 7 8 9 10	which confer an increased risk. Family history. BY MS. BOCKUS: Q. Do you know the odds ratios of any of the risk factors that you just identified of never having children, having
7 8 9 10 11 12	A. In terms of numbers? Q. Yes, sir. A. I don't know the I don't know the numbers. Q. What other risk factors are you familiar with for ovarian cancer? A. Well, certainly work with	6 7 8 9 10 11 12	which confer an increased risk. Family history. BY MS. BOCKUS: Q. Do you know the odds ratios of any of the risk factors that you just identified of never having children, having early menarche or late menopause?
7 8 9 10 11 12	A. In terms of numbers? Q. Yes, sir. A. I don't know the I don't know the numbers. Q. What other risk factors are you familiar with for ovarian cancer? A. Well, certainly work with asbestos is a risk factor, and we have a	6 7 8 9 10 11 12 13	which confer an increased risk. Family history. BY MS. BOCKUS: Q. Do you know the odds ratios of any of the risk factors that you just identified of never having children, having early menarche or late menopause? A. Right offhand, I don't know
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	Arch 1. Chip Co	ar som,	, M.D., FII.D.
	Page 334		Page 336
1	But also, some of these risk	1	Q. So you think you just ran into
2	factors are so common in the population that	2	her?
3	we can concoct large cohort studies that will	3	A. Yeah.
4	have can have very low relative risks,	4	Q. The other people that you
5	like on the order of 1.3 or even lower, and	5	identified that you discussed your report
6	still a significant result.	6	with, did you ask them to read your report?
7	So the more common a factor is,	7	A. I asked them to look at parts
8	the easier it is to do the research and the	8	of it, early drafts of it to let me know if
9	more likely you'll get a finding that's	9	they thought I was making sense.
10	relevant to interpretation.	10	Q. And did they offer you comments
11	Q. What pushes a talc particle	11	and suggestions for changes in your paper?
12	from the perineum into the vagina?	12	A. Not really. Mostly they gave
13	A. Probably mostly the law of mass	13	me a pat on the back and said: I think
14	action. It simply goes of its own volition.	14	you're doing a good job, just sort of beef
15	These small particles are always in motion	15	this part up, and what do you mean by this,
16	through molecular forces, and they simply	16	maybe I could rephrase that. That sort of
17	move in all directions, and some of them move	17	thing.
18	in that direction.	18	-
19	Q. Would that be true for any	19	Q. Did they give you written suggestions?
20	small particles applied to a woman's	20	
21	perineum?	21	A. No, these were all verbal comments.
22	1	22	
23		23	Q. Had you given them a hard copy
24	Q. Are you board certified in	24	of the portions of your report that you
24	medical toxicology?	24	wanted them to comment on?
	Page 335		Page 337
1	A. I'm not. I started practicing	1	A. Yes.
2	medical toxicology before there was a board	2	Q. And they didn't redline it or
3	in the specialty, and I've been grandfathered	3	make draw arrows or anything like that for
4	into the profession as a member of the	4	you?
5	American College of Medical Toxicology.	5	A. I think actually George Delclos
6	Q. How long did you talk to	6	did draw some or make some notes on there
7	Dr. Ness about her paper?	7	and hand it back to me, and I incorporated
8	A. About her paper, probably a	8	those into my electronic version.
9	minute and a half. About all kinds of other	9	Q. Do you still have George's
10	things, for a while.	10	notes to you?
11	Q. What other kinds of things?	11	A. No, I don't.
12	A. Mostly personal things that had	12	Q. Is he the only one out of the
13	nothing to do with talc or this case.	13	people that you asked to look at it who gave
14	Q. How long do you think that	14	you handwritten notes?
15	conversation was?	15	A. Yes, I think so.
16	A. Well, with Dr. Ness, nothing	16	Q. Have you seen the term
17	lasts very long, so I would say ten minutes	17	"intrinsic elimination system" regarding the
18	at the most.	18	ovary in any of the publications that you've
19		19	read?
エン	Q. Okay. Did you call her?A. No. She's she comes and	20	A. I don't know, I may have.
20	A. INU. SHE'S SHE COINES AND		
20			
21	goes in the same building where I office, and	21	Q. Can you think of one in
21 22	goes in the same building where I office, and my office is just on the opposite side of the	22	particular that discusses that characteristic
21	goes in the same building where I office, and	1	The state of the s

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discuss migration to the ovary. It would probably be a talc paper, though. I don't sexhooks? 4 Q. Did you consult any gynecologic textbooks? 5 A. No, I didn't. I may have looked at some diagrams on the Internet. 6 Q. Okay. Did you consult any gynecologic oncology textbooks? 6 A. No, I didn't. I may have looked at some diagrams on the Internet. 7 Q. Okay. Did you consult any gynecologic oncology textbooks? 8 Q. Okay. Did you consult any gynecologic oncology textbooks? 9 question of whether does tale increase a woman's risk for ovarian cancer? 11 Q. Would that be important to you to know their position? 12 A. No, I don't. 13 A. No, I don't. 14 Q. Would that be important to you to know their position? 15 A. No, I don't think so. 16 Q. Do you know the position of tale increases a woman's risk of ovarian cancer? 22 A. I don't know that either. 23 A. I don't know that either. 24 That's not something I've looked at. Page 339 1 Q. Would that be important to you? 24 A. Well, I saw this actually when a textivity, where they modeled the — the application of tale tump powder and did some calculations based on the amount of substance that was used, and they measured it in things like shakes and—and then quantified the amount that was lost from the container to determine what an application of the tendent quantified the amount that was lost from the container to determine what an application of the tendent of the ton the modeling process. 9 Q. Would that be important to you to know their position of the use of — perincal use of tale increases a woman's risk of ovarian and then quantified the amount of tale um powder from a single shake the dead up on a woman's perineum, did you? A. No, I don't think so. 9 Q. Do you know the position of a particle in biological fluids, which would go to the length of time a particle of tale remains in the ovary once it gest through the amount of all put the application and they measured the amount of whether does tale interests on the ovary longer tha		Page 338		Page 340
probably be a tale paper, though. I don't recall seeing it anywhere. Q. Did you consult any synecologic textbooks? A. No, I didn't. I may have looked at some diagrams on the Internet. Q. Okay. Did you consult any a have looked at some diagrams on the Internet. Q. Okay. Did you consult any sprecologic coclogic extbooks? A. No, I didn't. I may have looked at some diagrams on the Internet. Q. Okay. Did you consult any sprecologic coclogic extbooks? A. No textbooks no. 10 A. No textbooks no. 11 Q. Do you know the position of the guestion of whether does tale increase a woman's risk for ovarian cancer? 12 A. No, I don't. Q. Would that be important to you to know their position? 13 A. No, I don't think so. 14 Q. Do you know the position of tale increases a woman's risk for ovarian cancer? 15 A. No, I don't think so. 16 Q. Do you know the position of tale increases a woman's risk of ovarian cancer? 21 A. No, I don't think so. 22 cancer? 23 A. J don't know that either. 24 That's not something I've looked at. Page 339 Page 341 Q. Would that be important to you? A. No, I don't know that either. Page 339 Page 341 Q. Would that be important to you? A. No, I don't know that either. Page 339 Page 341 Q. Would that be important to you? A. No, I don't know that either. Page 339 Page 341	1		1	
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6 A. No, I didn't, I may have 7 looked at some diagrams on the Internet. 8 Q. Okay. Did you consult any 9 gynecologic oncology textbooks? 9 day on the Internet. 10 A. Not textbooks, no. 11 Q. Do you know the position of the 12 Society of Gynecologic Oncologists on the 13 question of whether does tale increase a 14 woman's risk for ovarian cancer? 14 woman's risk for ovarian cancer? 15 A. No, I don't think so. 16 Q. Would that be important to you 17 to know their position? 18 A. No, I don't think so. 19 Q. Do you know the position of 20 ACOG on whether the use of ~ perineal use of 21 tale increases a woman's risk of ovarian 22 cancer? 23 A. I don't know that either. 24 That's not something I've looked at. Page 339 1 Q. Would that be important to you? 2 A. No. 3 Q. Do you have any scientific text 4 that suggests that an inert particle resides 5 on the ovary longer than it does in the 6 cervix? 7 A. Well, I have I have a paper 8 that relates to the time for dissolution of a 9 particle in biological fluids, which would go 10 to the length of time a particle of tale 11 remains in the ovary once it gets there. 12 But I don't have I don't 13 know that I have a scientific paper that 14 specifically says that it stays in the ovary 15 longer than it stays in the ovary 16 Q. You testified that you 17 understand ther quantified the amount of ale, I guess from a 18 single use, that ended up and hen quantified the amount that was lost from the amount of tale, I guess from a 19 single use, that endes up on the perineum. 20 Did I understand that 21 correctly? 22 A. Yes. 23 Q. Can you tell me what those 24 Can you tell me what those 25 John think anything would be 26 tale unapproach and the quantify the amount of tale, I guess from a 27 single use, that ended up and here quantify the amount of tale, I guess from a 28 single use, that ended up adhered to the underwear ended up adhered to the perineum. 29 Did I understand ther 20 Can you tell me what those 21 A. Yes. 22 A. Yes. 23 Q. Can you tell me what those				
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8 Q. Okay. Did you consult any 9 gynecologic oncology textbooks? 10 A. Not textbooks, no. 11 Q. Do you know the position of the 12 Society of Gynecologic Oncologists on the 13 question of whether does talc increase a 14 woman's risk for ovarian cancer? 15 A. No, I don't. 16 Q. Would that be important to you 17 to know their position? 18 A. No, I don't think so. 19 Q. Do you know the position of 20 ACOG on whether the use of – perineal use of 21 talc increases a woman's risk of ovarian 22 cancer? 23 A. I don't know that either. 24 That's not something I've looked at. Page 339 1 Q. Would that be important to you? 2 A. No. 3 Q. Do you have any scientific text 4 that suggests that an inert particle resides 5 on the ovary longer than it does in the 6 cervix? 7 A. Well, I have – I have a paper 8 that relates to the time for dissolution of a 9 particle in biological fluids, which would go 10 to the length of time a particle of falc 11 remains in the ovary once it gets there. 12 But I don't have – I don't 13 know that I have a scientific paper that 14 specifically says that it stays in the ovary 15 longer than it stays in the cervix. 16 Q. You destified the amount of talc, I guess from a 17 single use, that ends up on the perineum. 18 they measured it in things like amount that was lost from the contine that and medical part that application amount was. 11 don't think they were able to 20 boyond that they were able to 20 beyond that them what an application amount was. 16 I don't think they were able to 20 Long od idhat attempted to quantify the amount of the length of the mount of the length of time a particle of realc 22 and the quantified the amount of talc, I guess from a 23 single use, that ends up on the perineum. 24 There we an attempt two underwear with they were anywhere that attempts to quantify the amount of talc, I guess from a 25 single use, that ends up on the perineum. 26 Did I understand ther 27 Can Yes. 28 A. Yes. 29 Can you tell me what those				_
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10 A. Not textbooks, no. 11 Q. Do you know the position of the 12 Society of Gynecologic Oncologists on the 13 question of whether does talc increase a 14 woman's risk for ovarian cancer? 15 A. No, I don't. 16 Q. Would that be important to you 17 to know their position? 18 A. No, I don't think so. 19 Q. Do you know the position of 20 ACOG on whether the use of perineal use of 21 talc increases a woman's risk of ovarian 22 cancer? 23 A. I don't know that either. 24 That's not something I've looked at. 24 That's not something I've looked at. 25 Q. Do you have any scientific text 26 that suggests that an inert particle resides 27 A. Well, I have I have a paper 28 that relates to the time for dissolution of a particle in biological fluids, which would go to the length of time a particle of fale 29 particle in biological fluids, which would go to the length of time a particle of talc 20 pid I understand that 21 quentify the amount of talc, I guess from a single use, that ends up on a woman's perineum. 29 Did I understand that 20 Did I understand that 21 gape 339 21 Q. Would that be important to you? 22 that dead up on a woman's perineum what an application amount was. 22 Idon't think they were able to go beyond that pop beyond that pop beyond that particle to the amount of talcum powder from a single use that ends up on the perineum. 22 and that attempts to the important to you? 31 A. I don't know the position of a particle in biological fluids, which would go to the length of time a particle of talc 31 quantify the amount of talc, I guess from a single use, that ends up on the perineum. 32 Q. Can you tell me what those 33 quantify the amount of talc, I guess from a single use, that ends up on the perineum. 34 point think what they were interested in was proximity. 35 point in the modeling process. 36 Q. Can you tell me what those 37 particle in biological fluids, which would go to the length of time a particle of talc 38 quantify the amount of talc, I guess from a single use, that ends up on the perineum. 39				
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12 Society of Gynecologic Oncologists on the 13 question of whether does tale increase a 14 woman's risk for ovarian cancer? 15 A. No, I don't. 16 Q. Would that be important to you 16 Now their position? 17 to know their position? 18 A. No, I don't think so. 19 Q. Do you know the position of 20 ACOG on whether the use of - perineal use of 21 talc increases a woman's risk of ovarian 22 cancer? 23 A. I don't know that either. 23 A. I don't know that either. 24 That's not something I've looked at. Page 339 1 Q. Would that be important to you? 2 that's not something I've looked at. Page 339 1 Q. Would that be important to you? 2 that's not something I've looked at. Page 339 1 Q. Would that be important to you? 3 Q. Do you have any scientific text 4 that suggests that an inert particle resides 5 on the ovary longer than it does in the 6 cervix? A. Well, I have — I have a paper 8 that relates to the time for dissolution of a 9 particle in biological fluids, which would go 10 to the length of time a particle of talc 11 remains in the ovary once it gets there. 12 But I don't have — I don't 13 know that I have a scientific paper that 14 specifically says that it stays in the ovary 15 longer than it stays in the ovary 16 Q. You testified that you 17 understand ther have been some attempts to 18 quantify the amount of talc, I guess from a single use, that ends up on the perineum. 20 Did I understand that 21 correctly? 22 A. Yes. 23 Q. Can you tell me what those 24 I don't think they were able to go beyond that point in the modeling process. 29 Did Ond't hink they were interested in the amount of talcum powder from a single use that ends up on the perineum. 21 point in the modeling process. 24 Dr. You don't know that end the manunt of talcum powder from a single use that ends up on the perineum. 29 Did I understand that 20 Did I understand that 21 correctly? 22 A. Yes. 23 Q. Can you tell me what those 24 I don't think they were able to quantify the amount of talc, I guess from a single use, that ends up on the perine		· · · · · · · · · · · · · · · · · · ·		
question of whether does tale increase a woman's risk for ovarian cancer? A. No, I don't. B. Q. Would that be important to you to know their position? A. No, I don't think so. Q. Do you know the position of Q. The second of the position of tale, I guess from a single use, that ended up on a woman's perineum? Page 339 Page 341 Successful. These were clothed subjects, so These were clothed subjects, so Athat adsa another factor to the calculation. BY MS. BOCKUS: Q. Is that the only experiment that you've seen anywhere that attempts to quantify the amount of talcum powder from a single shake that adsa another factor to the calculation. BY MS. BOCKUS: Q. Is that the only experiment that you've seen anywhere that attempts to quantify the amount of talcum powder from a single substated that you to the length of time a particle of talc Tremains in the ovary once it gets there. But I don't have I don't that suggests that an inert particle of talc Tremains in the ovary once it gets there. But I don't have I don't that relates to the time for dissolution of a particle in biological fluids, which would go to to the length of time a particle of talc Tremains in the ovary once it gets there. Q. You didn't know that that relates to the time for dissolution of a particle in biological fluids, which would go to the length of time a particl				**
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specifically says that it stays in the ovary longer than it stays in the cervix. 15 longer than it stays in the cervix. 16 Q. You testified that you 16 underwear ended up adhered to the woman's 17 understand there have been some attempts to 18 quantify the amount of talc, I guess from a 19 single use, that ends up on the perineum. 20 Did I understand that 21 correctly? 21 they measured the amount that adhered to the 22 A. Yes. 23 Q. Can you tell me what those 20 And do you recall what 21 percentage of the talc applied to the 25 underwear ended up adhered to the woman's 26 perineum? 27 A. I don't think I don't think 28 they measured the amount that adhered to the 29 perineum. I think what they were interested 20 in was proximity.				*
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17 understand there have been some attempts to 18 quantify the amount of talc, I guess from a 19 single use, that ends up on the perineum. 20 Did I understand that 21 correctly? 22 A. Yes. 23 Q. Can you tell me what those 21 perineum? 28 MS. O'DELL: Object to the 29 form. 20 A. I don't think I don't think 21 they measured the amount that adhered to the 22 perineum. I think what they were interested 23 in was proximity.		- · · · · · · · · · · · · · · · · · · ·		
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Q. Can you tell me what those 23 in was proximity.	19 20	Did I understand that	20	
	19 20 21	Did I understand that correctly?	20 21	they measured the amount that adhered to the
	19 20 21 22	Did I understand that correctly? A. Yes.	20 21 22	they measured the amount that adhered to the perineum. I think what they were interested
	19 20 21 22 23	Did I understand that correctly? A. Yes. Q. Can you tell me what those	20 21 22 23	they measured the amount that adhered to the perineum. I think what they were interested in was proximity.

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Page 342 Page 344 1 BY MS. BOCKUS: 1 A. Uh-huh. 2 Q. Okay. Can you tell me the 2 And echoing what my colleagues 3 names of the environmental websites that have 3 have said today, if there's at any point I 4 4 been talking about IARC revisiting their ask a question that you do not understand, 5 just stop me and ask me to rephrase it or let 5 classification of talc? 6 6 A. There are -- there are a number me know otherwise, okay? 7 of Twitter feeds and websites that carry on 7 A. I will. 8 8 this kind of discussion. Science Interest is O. Thanks. 9 one of them. I think IARC Watch is another 9 So going back shortly to your 10 10 one. I have -- I get e-mails about some of scope of work, do you teach any coursework on 11 these and end up going into them for a period 11 talc or ovarian cancer? of time and seeing if they have anything A. I teach some general courses. 12 12 13 interesting going on. Some of them are 13 Up until last spring I taught a general 14 searchable. 14 environmental health course for graduate 15 15 students in the Master of Public Health And then I get e-mails from the 16 ones that I visit about other ones. So I 16 program at the School of Public Health, and 17 17 spend as much of my time deleting these in that course we did touch on things like 18 e-mails without reading them as I do actually 18 environmental exposures that would include 19 viewing the material. 19 minerals of various varieties, but it was 20 Q. So fair to say this is just 20 very cursory. 21 21 chatter you've seen on the Internet in these O. And was that curriculum 22 different chat rooms or Twitter accounts that 22 specific to environmental and industrial 23 23 you visit from time to time? products or minerals as opposed to consumer 24 A. It's all Internet based, yes. 24 products? Page 343 Page 345 1 MS. BOCKUS: Okay. I think 1 A. We actually did touch on other 2 that's all I have. Thank you. 2 consumer products as well in terms of the 3 3 MS. O'DELL: Why don't we take significant environmental problem that we a short break. We've been going about 4 have currently, but -- regarding the huge 4 5 5 two hours. volume of personal care products that goes 6 MR. ZELLERS: Do you have 6 into our aqueous waste stream and how that's 7 7 affecting the aquatic environment as well as questions? groundwater and so forth. 8 8 MS. APPEL: I do, but --9 9 MS. O'DELL: Yeah, do you As a matter of fact, in that 10 10 have -course, as part of the culmination of the 11 MS. APPEL: I don't have a lot. 11 course, there are student workgroups that 12 MS. O'DELL: Okay. Sure. Why 12 develop presentations on a particular topic, don't you go ahead, and then we'll 13 13 and the topic of personal care products has 14 take a break. We have been going 14 been a favorite choice for the last several 15 15 about two hours, but, Renée, please. vears. 16 If you're okay, Doctor. 16 But your curriculum did not 17 THE WITNESS: I'm fine. 17 include talc among those products? 18 **EXAMINATION** 18 MS. O'DELL: Object to the 19 BY MS. APPEL: 19 form. 20 20 A. I think talc may have been Q. It's been a while since we did 21 21 represented as an individual mineral on a introductions, so just as a reminder, my name 22 is Renée Appel and I'm here on behalf of 22 slide that listed many minerals. 23 Seyfarth Shaw and I represent Personal Care 23 BY MS. APPEL: 24 Products, counsel. 24 Q. Earlier today you had mentioned

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	Page 346		Page 348
-		_	
1	a shared file. Is that shared file something	1	accumulating information in the draft as a
2	that you created or plaintiffs' counsel	2	result of my review of the literature.
3	created?	3	So if I had to separate things
4	A. It's something that I think	4	out, I would say that, by far, the most of
5	plaintiffs' counsel created for me to be able	5	the time has been spent in reading articles
6	to send them documents and receive documents,	6	and reviewing them and comparing them with
7	and it's a Dropbox share file. It's at	7	other articles, and a comparatively small
8	this point I think it might be mine. I'm not	8	amount of time has been spent in drafting the
9	sure just exactly who's in charge of that or	9	report.
10	runs it, but it comes directly into my	10	Although there were some
11	Dropbox file.	11	strings of activity which was all report
12	I know I had to boost my	12	drafting basically, I would say probably 85
13	subscription to Dropbox in order to hold the	13	to 90% was research, seeking articles,
14	2 gigabytes of data from that we were	14	reading them, reviewing them, and comparing
15	putting into there.	15	them.
16	Q. Is there anything from that	16	Q. And you also testified earlier
17	Dropbox file that you relied upon in forming	17	today that you discarded information not
18	your opinion in your report that you have not	18	relevant or interesting to you.
19	already provided to defense counsel?	19	How did you make that
20	A. No, everything that was in that	20	determination?
21	Dropbox that I've relied upon has been	21	MS. O'DELL: Objection to the
22	identified here.	22	form.
23	Q. Who prepared Exhibit B to your	23	A. The things that I discarded did
24	report?	24	not seem to fit into my gestalt of the
	Page 347		Page 349
1		1	
	A. Exhibit B was a list of	1	understanding of this question and the
		1 2	understanding of this question and the opinions that I wanted to express. They may
2	articles from the research literature	2	opinions that I wanted to express. They may
	articles from the research literature included in the Dropbox that that I think		opinions that I wanted to express. They may have been interesting information and useful
2 3 4	articles from the research literature included in the Dropbox that that I think does not I don't know whether it includes	2 3 4	opinions that I wanted to express. They may have been interesting information and useful for some purposes, but not for this
2	articles from the research literature included in the Dropbox that that I think does not I don't know whether it includes the referenced articles from my report or	2 3	opinions that I wanted to express. They may have been interesting information and useful
2 3 4 5	articles from the research literature included in the Dropbox that that I think does not I don't know whether it includes	2 3 4 5	opinions that I wanted to express. They may have been interesting information and useful for some purposes, but not for this particular report.
2 3 4 5 6	articles from the research literature included in the Dropbox that that I think does not I don't know whether it includes the referenced articles from my report or not, but they were all part of the same	2 3 4 5 6	opinions that I wanted to express. They may have been interesting information and useful for some purposes, but not for this particular report. BY MS. APPEL:
2 3 4 5 6 7	articles from the research literature included in the Dropbox that that I think does not I don't know whether it includes the referenced articles from my report or not, but they were all part of the same collection of research articles and	2 3 4 5 6 7	opinions that I wanted to express. They may have been interesting information and useful for some purposes, but not for this particular report. BY MS. APPEL: Q. Was some of that information
2 3 4 5 6 7 8	articles from the research literature included in the Dropbox that that I think does not I don't know whether it includes the referenced articles from my report or not, but they were all part of the same collection of research articles and supplemental documents.	2 3 4 5 6 7 8	opinions that I wanted to express. They may have been interesting information and useful for some purposes, but not for this particular report. BY MS. APPEL: Q. Was some of that information that you discarded based on relevancy or that
2 3 4 5 6 7 8 9	articles from the research literature included in the Dropbox that that I think does not I don't know whether it includes the referenced articles from my report or not, but they were all part of the same collection of research articles and supplemental documents. Q. And my question, Dr. Carson,	2 3 4 5 6 7 8 9	opinions that I wanted to express. They may have been interesting information and useful for some purposes, but not for this particular report. BY MS. APPEL: Q. Was some of that information that you discarded based on relevancy or that you determined was not of interest
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2 3 4 5 6 7 8 9 10 11	articles from the research literature included in the Dropbox that that I think does not I don't know whether it includes the referenced articles from my report or not, but they were all part of the same collection of research articles and supplemental documents. Q. And my question, Dr. Carson, was: Who prepared that exhibit? A. The exhibit was prepared by the plaintiffs' attorneys.	2 3 4 5 6 7 8 9 10 11	opinions that I wanted to express. They may have been interesting information and useful for some purposes, but not for this particular report. BY MS. APPEL: Q. Was some of that information that you discarded based on relevancy or that you determined was not of interest information that may have been different than your opinions? A. No. I didn't discard any
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2 3 4 5 6 7 8 9 10 11 12 13	articles from the research literature included in the Dropbox that that I think does not I don't know whether it includes the referenced articles from my report or not, but they were all part of the same collection of research articles and supplemental documents. Q. And my question, Dr. Carson, was: Who prepared that exhibit? A. The exhibit was prepared by the plaintiffs' attorneys. Q. You testified earlier that you have spent approximately 150 to 180 hours in	2 3 4 5 6 7 8 9 10 11 12 13 14	opinions that I wanted to express. They may have been interesting information and useful for some purposes, but not for this particular report. BY MS. APPEL: Q. Was some of that information that you discarded based on relevancy or that you determined was not of interest information that may have been different than your opinions? A. No. I didn't discard any research because the opinions provided differed from my own. These were things that
2 3 4 5 6 7 8 9 10 11 12 13 14 15	articles from the research literature included in the Dropbox that that I think does not I don't know whether it includes the referenced articles from my report or not, but they were all part of the same collection of research articles and supplemental documents. Q. And my question, Dr. Carson, was: Who prepared that exhibit? A. The exhibit was prepared by the plaintiffs' attorneys. Q. You testified earlier that you have spent approximately 150 to 180 hours in your expert retention work; is that correct?	2 3 4 5 6 7 8 9 10 11 12 13 14 15	opinions that I wanted to express. They may have been interesting information and useful for some purposes, but not for this particular report. BY MS. APPEL: Q. Was some of that information that you discarded based on relevancy or that you determined was not of interest information that may have been different than your opinions? A. No. I didn't discard any research because the opinions provided differed from my own. These were things that really were irrelevant to the question.
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	articles from the research literature included in the Dropbox that that I think does not I don't know whether it includes the referenced articles from my report or not, but they were all part of the same collection of research articles and supplemental documents. Q. And my question, Dr. Carson, was: Who prepared that exhibit? A. The exhibit was prepared by the plaintiffs' attorneys. Q. You testified earlier that you have spent approximately 150 to 180 hours in your expert retention work; is that correct? A. Correct. Q. Can you estimate what portion of that time was spent researching versus what portion of time was spent actually drafting your expert report?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	opinions that I wanted to express. They may have been interesting information and useful for some purposes, but not for this particular report. BY MS. APPEL: Q. Was some of that information that you discarded based on relevancy or that you determined was not of interest information that may have been different than your opinions? A. No. I didn't discard any research because the opinions provided differed from my own. These were things that really were irrelevant to the question. I remember finding an awful lot of geological research stuff that just didn't have any relevance to the question. Because I used such broad search terms, I ended up pulling in a whole
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	articles from the research literature included in the Dropbox that that I think does not I don't know whether it includes the referenced articles from my report or not, but they were all part of the same collection of research articles and supplemental documents. Q. And my question, Dr. Carson, was: Who prepared that exhibit? A. The exhibit was prepared by the plaintiffs' attorneys. Q. You testified earlier that you have spent approximately 150 to 180 hours in your expert retention work; is that correct? A. Correct. Q. Can you estimate what portion of that time was spent researching versus what portion of time was spent actually drafting your expert report? A. Those two things are in some	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	opinions that I wanted to express. They may have been interesting information and useful for some purposes, but not for this particular report. BY MS. APPEL: Q. Was some of that information that you discarded based on relevancy or that you determined was not of interest information that may have been different than your opinions? A. No. I didn't discard any research because the opinions provided differed from my own. These were things that really were irrelevant to the question. I remember finding an awful lot of geological research stuff that just didn't have any relevance to the question. Because I used such broad search terms, I ended up pulling in a whole lot of things that were not necessary or
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	articles from the research literature included in the Dropbox that that I think does not I don't know whether it includes the referenced articles from my report or not, but they were all part of the same collection of research articles and supplemental documents. Q. And my question, Dr. Carson, was: Who prepared that exhibit? A. The exhibit was prepared by the plaintiffs' attorneys. Q. You testified earlier that you have spent approximately 150 to 180 hours in your expert retention work; is that correct? A. Correct. Q. Can you estimate what portion of that time was spent researching versus what portion of time was spent actually drafting your expert report? A. Those two things are in some ways difficult to separate because I would	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	opinions that I wanted to express. They may have been interesting information and useful for some purposes, but not for this particular report. BY MS. APPEL: Q. Was some of that information that you discarded based on relevancy or that you determined was not of interest information that may have been different than your opinions? A. No. I didn't discard any research because the opinions provided differed from my own. These were things that really were irrelevant to the question. I remember finding an awful lot of geological research stuff that just didn't have any relevance to the question. Because I used such broad search terms, I ended up pulling in a whole lot of things that were not necessary or useful, and those just went in the trash.

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	Page 350		Page 352
1	cancer; is that correct?	1	usually administer to my patients, and I have
2	A. Not knowingly, not because of	2	plans to add that as a question in my
3	ovarian cancer.	3	environmental exposure survey. Which I
4	Q. Have you ever diagnosed any	4	haven't done already, but will as soon as I
5	patients with ovarian cancer?	5	get the opportunity.
6	A. I think when I was in medical	6	BY MS. APPEL:
7	school or residency, I probably participated	7	Q. You testified earlier today
8	in that on several patients.	8	that you do not believe there was ever a
9	Q. Have you ever instructed a	9	point where talcum powder did not contain
10	patient not to use talcum powder products?	10	asbestos, correct?
11	A. I hadn't up until a month or	11	A. Yes.
12	two ago, but I've been asking people about	12	Q. So in forming your opinion in
13	about their talcum powder use just as sort of	13	your report, you've assumed that the talcum
14	a curiosity in mentioning that there might be	14	powder does contain asbestos, correct?
15	a risk.	15	MS. O'DELL: Object to the
16	Q. Do you ask that of all your	16	form.
17	patients?	17	A. Well, I think the asbestos
18	A. I would say no, I don't usually	18	contribution to this whole issue is important
19	ask the men that, but I probably should.	19	and significant. I think there's good
20	Q. And have the responses to those	20	evidence that whatever we call talcum powder
21	inquiries of your female patients and their	21	is carcinogenic and responsible for ovarian
22	talcum product use, has that been used at all	22	cancer as a cause of ovarian cancer, but I
23	to inform your opinions in this case?	23	can't say I can't say based on looking at
24	A. I don't think so. There have	24	a can of talcum powder whether or not it has
 	Page 351		Page 353
1	been very few that I have asked that question	1	asbestos in it or how much.
2	in the last month or so. I've had a limited	2	BY MS. APPEL:
3	clinic schedule during this period of time.	3	Q. Have you formed an opinion,
4	We had the holidays and other things, so I	4	Dr. Carson, on whether there's a relationship
5	haven't seen that many patients.	5	between pure talc and ovarian cancer?
6	And of those I've asked about	6	MS. O'DELL: Objection to form.
7	it, it seems about half of the women have had	7	A. My opinion is there is, but
8	a history of using talcum powder.	8	that's based on the research reports that
9	Q. And of those women that are	9	have been done using so-called pure talc,
10	using have told you that they have used	10	talcum powder, and I am I my opinion is
11	talcum powder, are those women diagnosed with	11	that it's unlikely that those test substances
12	ovarian cancer?	12	actually are pure talc.
13	A. No.	13	BY MS. APPEL:
14	Q. So suffice to say the inquiry	14	Q. So again, Dr. Carson, in
15	that you've asked of your female patients	15	forming your opinions, you have done so on
16	concerning their talcum use has nothing to do	16	the belief that all the talc powder products
	with the question that you've been posed in	17	or just pure talc do, in fact, contain
17		18	asbestos?
17 18	this particular litigation?		
	MS. O'DELL: Object to the	19	MS. O'DELL: Objection to form.
18	-	20	A. It is my opinion that all
18 19 20 21	MS. O'DELL: Object to the form. A. Actually, that's the only	20 21	A. It is my opinion that all talcum powder products do contain a certain
18 19 20 21 22	MS. O'DELL: Object to the form. A. Actually, that's the only reason I've been asking them. It's not	20 21 22	A. It is my opinion that all talcum powder products do contain a certain amount of asbestos, even if it's extremely
18 19 20 21	MS. O'DELL: Object to the form. A. Actually, that's the only	20 21	A. It is my opinion that all talcum powder products do contain a certain

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14 MR. ZELLERS: Move to strike as 15 nonresponsive. 16 MS. APPEL: Respectfully 17 MS. BOCKUS: Is he finished? 18 MR. ZELLERS: I don't think so. 19 THE WITNESS: I can go on. 20 BY MS. APPEL: 20 BY MS. APPEL: 21 Q. Yeah. My question was more 22 narrow, and I was analogizing your opinion as 23 to talcum powder and was asking about other 25 MS. O'DELL: Objection to form. 26 A. It will cause an increase in risk of cancer. Doesn't necessarily cause cancer in everybody. 21 PSY MS. APPEL: 22 Q. Okay. Are you aware that Saed has been hired by plaintiffs' counsel in this litigation? 23 A. I am. And when I misspoke			12	
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18 MR. ZELLERS: I don't think so. 19 THE WITNESS: I can go on. 20 BY MS. APPEL: 20 Q. Okay. Are you aware that Saed 21 Q. Yeah. My question was more 22 narrow, and I was analogizing your opinion as 23 to talcum powder and was asking about other 24 cancer in everybody. 25 BY MS. APPEL: 26 Q. Okay. Are you aware that Saed 27 has been hired by plaintiffs' counsel in this 28 litigation? 29 A. I am. And when I misspoke				
19 THE WITNESS: I can go on. 20 BY MS. APPEL: 21 Q. Yeah. My question was more 22 narrow, and I was analogizing your opinion as 23 to talcum powder and was asking about other 29 BY MS. APPEL: 20 Q. Okay. Are you aware that Saed 21 has been hired by plaintiffs' counsel in this 22 litigation? 23 A. I am. And when I misspoke				· · · · · · · · · · · · · · · · · · ·
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23 to talcum powder and was asking about other 23 A. I am. And when I misspoke				* *
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24 2B classifications, and my example 24 earlier today regarding the Taher paper, I				
	24	2B classifications, and my example	24	earlier today regarding the Taher paper, I

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	Page 362		Page 364
1	was thinking of the Saed paper.	1 2	CERTIFICATE I, MICHAEL E. MILLER, Fellow of
2	Q. Okay. Last question: Counsel		the Academy of Professional Reporters,
3	was asking you about the migration process,	3	Registered Diplomate Reporter, Certified Realtime Reporter, Certified Court Reporter
4	and you mentioned that in the course of	4	and Notary Public, do hereby certify that prior to the commencement of the examination,
5	particles moving up the track, that some of	5	ARCH I. "CHIP" CARSON, M.D., Ph.D. was duly
6	it may come back out even after it reaches	6	sworn by me to testify to the truth, the whole truth and nothing but the truth.
7	the fluid surrounding the ovaries, correct?	7	I DO FURTHER CERTIFY that the foregoing is a verbatim transcript of the
8	A. Yes.	8	testimony as taken stenographically by and
9	Q. So if particles have the	9	before me at the time, place and on the date hereinbefore set forth, to the best of my
10	ability to come back out, that means that	10	ability.
11	there is, in fact, some form of an intrinsic		I DO FURTHER CERTIFY that pursuant
12	elimination system.	11	to FRCP Rule 30, signature of the witness was not requested by the witness or other party
13	A. Well, if this is all based on	12 13	before the conclusion of the deposition. I DO FURTHER CERTIFY that I am
14	mass action, it would not necessarily be an		neither a relative nor employee nor attorney
15	intrinsic elimination system, and I believe	14	nor counsel of any of the parties to this action, and that I am neither a relative nor
16	that talc particles, once they produce an	15	employee of such attorney or counsel, and that I am not financially interested in the
17		16 17	action.
18	inflammatory response, they become	17	
18	sequestered within that inflammatory milieu	19	MICHAEL E. MILLER, FAPR, RDR, CRR Fellow of the Academy of Professional Reporters
	and no longer are available for movement back		NCRA Registered Diplomate Reporter
20	out into the fluid.	20	NCRA Certified Realtime Reporter Certified Court Reporter
21	I'm sure there's some small	21	Notary Public in and for the
22	percentage of them that are an exception to	22	State of Texas
23	that, but for the majority, that would be the	23	My Commission Expires: 7/9/2020
24	case.	24	Dated: January 22, 2019
	Page 363		Page 365
1	MS. APPEL: Okay. That's all I	1	INSTRUCTIONS TO WITNESS
2	have. Thank you, Dr. Carson.	2	
3	MS. TINSLEY: I don't have any	3	Please read your deposition over
4	questions.	4	carefully and make any necessary corrections.
5	MS. O'DELL: Okay. Why don't	5	You should state the reason in the
6	we take a short break.	6	appropriate space on the errata sheet for any
7	THE VIDEOGRAPHER: Off the	7	corrections that are made.
8	record at 5:37, end of Tape 4.	8	After doing so, please sign the
9	(Recess taken, 5:37 p.m. to	9	errata sheet and date it.
10	5:44 p.m.)	10	You are signing same subject to
11	THE VIDEOGRAPHER: We're on the	11	the changes you have noted on the errata
12	record at 5:44, beginning of Tape 5.	12	sheet, which will be attached to your
13	MS. O'DELL: Dr. Carson, I	13	deposition.
14	don't have any questions, so this will	14	It is imperative that you return
	• •	15	the original errata sheet to the deposing
15 16	conclude your deposition.	16	attorney within thirty (30) days of receipt
16	MR. ZELLERS: Thank you,	17	• • • • • • • • • • • • • • • • • • • •
17	Doctor.		of the deposition transcript by you. If you
18	THE VIDEOGRAPHER: Going off	18	fail to do so, the deposition transcript may
19	the record, 5:44. End of deposition,	19	be deemed to be accurate and may be used in
	end of Tape 5.	20	court.
20	/		
20 21	(Proceedings recessed at	21	
20 21 22	5:45 p.m.)	22	
20 21	· · ·		

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	23		
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ACKNOWLEDGMENT OF DEPONENT			
I, ARCH I. "CHIP" CARSON, M.D.,			
Ph.D., do hereby certify that I have read the foregoing pages and that the same is a			
correct transcription of the answers given by			
me to the questions therein propounded,			
except for the corrections or changes in form			
or substance, if any, noted in the attached			
Errata Sheet.			
ARCH I. "CHIP" CARSON, M.D., Ph.D. DATE			
Subscribed and sworn to before me this			
day of , 20 .			
My commission expires:			
- 			
N			
Notary Public			
	1		

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Exhibit 20

THIRD EDITION

MODERN EPIDEMIOLOGY

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CHAPTER 2

Causation and Causal Inference

Kenneth J. Rothman, Sander Greenland, Charles Poole, and Timothy L. Lash

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CAUSALITY

A rudimentary understanding of cause and effect seems to be acquired by most people on their own much earlier than it could have been taught to them by someone else. Even before they can speak, many youngsters understand the relation between crying and the appearance of a parent or other adult, and the relation between that appearance and getting held, or fed. A little later, they will develop theories about what happens when a glass containing milk is dropped or turned over, and what happens when a switch on the wall is pushed from one of its resting positions to another. While theories such as these are being formulated, a more general causal theory is also being formed. The more general theory posits that some events or states of nature are causes of specific effects. Without a general theory of causation, there would be no skeleton on which to hang the substance of the many specific causal theories that one needs to survive.

Nonetheless, the concepts of causation that are established early in life are too primitive to serve well as the basis for scientific theories. This shortcoming may be especially true in the health and social sciences, in which typical causes are neither necessary nor sufficient to bring about effects of interest. Hence, as has long been recognized in epidemiology, there is a need to develop a more refined conceptual model that can serve as a starting point in discussions of causation. In particular, such a model should address problems of multifactorial causation, confounding, interdependence of effects, direct and indirect effects, levels of causation, and systems or webs of causation (MacMahon and Pugh, 1967; Susser, 1973). This chapter describes one starting point, the sufficient-component cause model (or sufficient-cause model), which has proven useful in elucidating certain concepts in individual mechanisms of causation. Chapter 4 introduces the widely used potential-outcome or counterfactual model of causation, which is useful for relating individual-level to population-level causation, whereas Chapter 12 introduces graphical causal models (causal diagrams), which are especially useful for modeling causal systems.

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Except where specified otherwise (in particular, in Chapter 27, on infectious disease), throughout the book we will assume that disease refers to a nonrecurrent event, such as death or first occurrence of a disease, and that the outcome of each individual or unit of study (e.g., a group of persons) is not affected by the exposures and outcomes of other individuals or units. Although this assumption will greatly simplify our discussion and is reasonable in many applications, it does not apply to contagious phenomena, such as transmissible behaviors and diseases. Nonetheless, all the definitions and most of the points we make (especially regarding validity) apply more generally. It is also essential to understand simpler situations before tackling the complexities created by causal interdependence of individuals or units.

A MODEL OF SUFFICIENT CAUSE AND COMPONENT CAUSES

To begin, we need to define *cause*. One definition of the cause of a specific disease occurrence is an antecedent event, condition, or characteristic that was necessary for the occurrence of the disease at the moment it occurred, given that other conditions are fixed. In other words, a cause of a disease occurrence is an event, condition, or characteristic that preceded the disease onset and that, had the event, condition, or characteristic been different in a specified way, the disease either would not have occurred at all or would not have occurred until some later time. Under this definition, if someone walking along an icy path falls and breaks a hip, there may be a long list of causes. These causes might include the weather on the day of the incident, the fact that the path was not cleared for pedestrians, the choice of footgear for the victim, the lack of a handrail, and so forth. The constellation of causes required for this particular person to break her hip at this particular time can be depicted with the sufficient cause diagrammed in Figure 2-1. By sufficient cause we mean a complete causal mechanism, a minimal set of conditions and events that are sufficient for the outcome to occur. The circle in the figure comprises five segments, each of which represents a causal component that must be present or have occured in order for the person to break her hip at that instant. The first component, labeled A, represents poor weather. The second component, labeled B, represents an uncleared path for pedestrians. The third component, labeled C, represents a poor choice of footgear. The fourth component, labeled D, represents the lack of a handrail. The final component, labeled U, represents all of the other unspecified events, conditions, and characteristics that must be present or have occurred at the instance of the fall that led to a broken hip. For etiologic effects such as the causation of disease, many and possibly all of the components of a sufficient cause may be unknown (Rothman, 1976a). We usually include one component cause, labeled U, to represent the set of unknown factors.

All of the component causes in the sufficient cause are required and must be present or have occured at the instance of the fall for the person to break a hip. None is superfluous, which means that blocking the contribution of any component cause prevents the sufficient cause from acting. For many people, early causal thinking persists in attempts to find single causes as explanations for observed phenomena. But experience and reasoning show that the causal mechanism for any effect must consist of a constellation of components that act in concert (Mill, 1862; Mackie, 1965). In disease etiology, a sufficient cause is a set of conditions sufficient to ensure that the outcome will occur. Therefore, completing a sufficient cause is tantamount to the onset of disease. Onset here may refer to the onset of the earliest stage of the disease process or to any transition from one well-defined and readily characterized stage to the next, such as the onset of signs or symptoms.

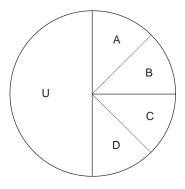


FIGURE 2–1 • Depiction of the constellation of component causes that constitute a sufficient cause for hip fracture for a particular person at a particular time. In the diagram, A represents poor weather, B represents an uncleared path for pedestrians, C represents a poor choice of footgear, D represents the lack of a handrail, and U represents all of the other unspecified events, conditions, and characteristics that must be present or must have occured at the instance of the fall that led to a broken hip.

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Consider again the role of the handrail in causing hip fracture. The absence of such a handrail may play a causal role in some sufficient causes but not in others, depending on circumstances such as the weather, the level of inebriation of the pedestrian, and countless other factors. Our definition links the lack of a handrail with this one broken hip and does not imply that the lack of this handrail by itself was sufficient for that hip fracture to occur. With this definition of cause, no specific event, condition, or characteristic is sufficient by itself to produce disease. The definition does not describe a complete causal mechanism, but only a component of it. To say that the absence of a handrail is a component cause of a broken hip does not, however, imply that every person walking down the path will break a hip. Nor does it imply that if a handrail is installed with properties sufficient to prevent that broken hip, that no one will break a hip on that same path. There may be other sufficient causes by which a person could suffer a hip fracture. Each such sufficient cause would be depicted by its own diagram similar to Figure 2–1. The first of these sufficient causes to be completed by simultaneous accumulation of all of its component causes will be the one that depicts the mechanism by which the hip fracture occurs for a particular person. If no sufficient cause is completed while a person passes along the path, then no hip fracture will occur over the course of that walk.

As noted above, a characteristic of the naive concept of causation is the assumption of a oneto-one correspondence between the observed cause and effect. Under this view, each cause is seen as "necessary" and "sufficient" in itself to produce the effect, particularly when the cause is an observable action or event that takes place near in time to the effect. Thus, the flick of a switch appears to be the singular cause that makes an electric light go on. There are less evident causes, however, that also operate to produce the effect: a working bulb in the light fixture, intact wiring from the switch to the bulb, and voltage to produce a current when the circuit is closed. To achieve the effect of turning on the light, each of these components is as important as moving the switch, because changing any of these components of the causal constellation will prevent the effect. The term necessary cause is therefore reserved for a particular type of component cause under the sufficient-cause model. If any of the component causes appears in every sufficient cause, then that component cause is called a "necessary" component cause. For the disease to occur, any and all necessary component causes must be present or must have occurred. For example, one could label a component cause with the requirement that one must have a hip to suffer a hip fracture. Every sufficient cause that leads to hip fracture must have that component cause present, because in order to fracture a hip, one must have a hip to fracture.

The concept of complementary component causes will be useful in applications to epidemiology that follow. For each component cause in a sufficient cause, the set of the other component causes in that sufficient cause comprises the complementary component causes. For example, in Figure 2–1, component cause A (poor weather) has as its complementary component causes the components labeled B, C, D, and U. Component cause B (an uncleared path for pedestrians) has as its complementary component causes the components labeled A, C, D, and U.

THE NEED FOR A SPECIFIC REFERENCE CONDITION

Component causes must be defined with respect to a clearly specified alternative or reference condition (often called a *referent*). Consider again the lack of a handrail along the path. To say that this condition is a component cause of the broken hip, we have to specify an alternative condition against which to contrast the cause. The mere presence of a handrail would not suffice. After all, the hip fracture might still have occurred in the presence of a handrail, if the handrail was too short or if it was old and made of rotten wood. We might need to specify the presence of a handrail sufficiently tall and sturdy to break the fall for the absence of that handrail to be a component cause of the broken hip.

To see the necessity of specifying the alternative event, condition, or characteristic as well as the causal one, consider an example of a man who took high doses of ibuprofen for several years and developed a gastric ulcer. Did the man's use of ibuprofen cause his ulcer? One might at first assume that the natural contrast would be with what would have happened had he taken nothing instead of ibuprofen. Given a strong reason to take the ibuprofen, however, that alternative may not make sense. If the specified alternative to taking ibuprofen is to take acetaminophen, a different drug that might have been indicated for his problem, and if he would not have developed the ulcer had he used acetaminophen, then we can say that using ibuprofen caused the ulcer. But ibuprofen did not cause

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his ulcer if the specified alternative is taking aspirin and, had he taken aspirin, he still would have developed the ulcer. The need to specify the alternative to a preventive is illustrated by a newspaper headline that read: "Rare Meat Cuts Colon Cancer Risk." Was this a story of an epidemiologic study comparing the colon cancer rate of a group of people who ate rare red meat with the rate in a group of vegetarians? No, the study compared persons who ate rare red meat with persons who ate highly cooked red meat. The same exposure, regular consumption of rare red meat, might have a preventive effect when contrasted against highly cooked red meat and a causative effect or no effect in contrast to a vegetarian diet. An event, condition, or characteristic is not a cause by itself as an intrinsic property it possesses in isolation, but as part of a causal contrast with an alternative event, condition, or characteristic (Lewis, 1973; Rubin, 1974; Greenland et al., 1999a; Maldonado and Greenland, 2002; see Chapter 4).

APPLICATION OF THE SUFFICIENT-CAUSE MODEL TO EPIDEMIOLOGY

The preceding introduction to concepts of sufficient causes and component causes provides the lexicon for application of the model to epidemiology. For example, tobacco smoking is a cause of lung cancer, but by itself it is not a sufficient cause, as demonstrated by the fact that most smokers do not get lung cancer. First, the term *smoking* is too imprecise to be useful beyond casual description. One must specify the type of smoke (e.g., cigarette, cigar, pipe, or environmental), whether it is filtered or unfiltered, the manner and frequency of inhalation, the age at initiation of smoking, and the duration of smoking. And, however smoking is defined, its alternative needs to be defined as well. Is it smoking nothing at all, smoking less, smoking something else? Equally important, even if smoking and its alternative are both defined explicitly, smoking will not cause cancer in everyone. So who is susceptible to this smoking effect? Or, to put it in other terms, what are the other components of the causal constellation that act with smoking to produce lung cancer in this contrast?

Figure 2–2 provides a schematic diagram of three sufficient causes that could be completed during the follow-up of an individual. The three conditions or events—A, B, and E—have been defined as binary variables, so they can only take on values of 0 or 1. With the coding of A used in the figure, its reference level, A=0, is sometimes causative, but its index level, A=1, is never causative. This situation arises because two sufficient causes contain a component cause labeled "A = 0," but no sufficient cause contains a component cause labeled "A = 1." An example of a condition or event of this sort might be A=1 for taking a daily multivitamin supplement and A=0 for taking no vitamin supplement. With the coding of B and E used in the example depicted by Figure 2–2, their index levels, B=1 and E=1, are sometimes causative, but their reference levels, B=0 and C=0, are never causative. For each variable, the index and reference levels may represent only two alternative states or events out of many possibilities. Thus, the coding of B might be B=1 for smoking 20 cigarettes per day for 40 years and B=0 for smoking 20 cigarettes per day for 20 years, followed by 20 years of not smoking. E might be coded E=1 for living in an urban neighborhood with low average income and high income inequality, and E=0 for living in an urban neighborhood with high average income and low income inequality.

A=0, B=1, and E=1 are individual component causes of the sufficient causes in Figure 2–2. U_1 , U_2 , and U_3 represent sets of component causes. U_1 , for example, is the set of all components other than A=0 and B=1 required to complete the first sufficient cause in Figure 2–2. If we decided not to specify B=1, then B=1 would become part of the set of components that are causally complementary to A=0; in other words, B=1 would then be absorbed into U_1 .

Each of the three sufficient causes represented in Figure 2–2 is minimally sufficient to produce the disease in the individual. That is, only one of these mechanisms needs to be completed for

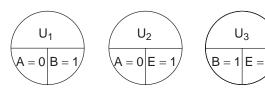


FIGURE 2–2 • Three classes of sufficient causes of a disease (sufficient causes I, II, and III from left to right).

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disease to occur (sufficiency), and there is no superfluous component cause in any mechanism (minimality)—each component is a required part of that specific causal mechanism. A specific component cause may play a role in one, several, or all of the causal mechanisms. As noted earlier, a component cause that appears in all sufficient causes is called a *necessary* cause of the outcome. As an example, infection with HIV is a component of every sufficient cause of acquired immune deficiency syndrome (AIDS) and hence is a necessary cause of AIDS. It has been suggested that such causes be called "universally necessary," in recognition that every component of a sufficient cause is necessary for that sufficient cause (mechanism) to operate (Poole 2001a).

Figure 2–2 does not depict aspects of the causal process such as sequence or timing of action of the component causes, dose, or other complexities. These can be specified in the description of the contrast of index and reference conditions that defines each component cause. Thus, if the outcome is lung cancer and the factor B represents cigarette smoking, it might be defined more explicitly as smoking at least 20 cigarettes a day of unfiltered cigarettes for at least 40 years beginning at age 20 years or earlier (B = 1), or smoking 20 cigarettes a day of unfiltered cigarettes, beginning at age 20 years or earlier, and then smoking no cigarettes for the next 20 years (B = 0).

In specifying a component cause, the two sides of the causal contrast of which it is composed should be defined with an eye to realistic choices or options. If prescribing a placebo is not a realistic therapeutic option, a causal contrast between a new treatment and a placebo in a clinical trial may be questioned for its dubious relevance to medical practice. In a similar fashion, before saying that oral contraceptives increase the risk of death over 10 years (e.g., through myocardial infarction or stroke), we must consider the alternative to taking oral contraceptives. If it involves getting pregnant, then the risk of death attendant to childbirth might be greater than the risk from oral contraceptives, making oral contraceptives a preventive rather than a cause. If the alternative is an equally effective contraceptive without serious side effects, then oral contraceptives may be described as a cause of death.

To understand prevention in the sufficient-component cause framework, we posit that the alternative condition (in which a component cause is absent) prevents the outcome relative to the presence of the component cause. Thus, a preventive effect of a factor is represented by specifying its causative alternative as a component cause. An example is the presence of A=0 as a component cause in the first two sufficient causes shown in Figure 2–2. Another example would be to define a variable, F (not depicted in Fig. 2–2), as "vaccination (F = 1) or no vaccination (F = 0)". Prevention of the disease by getting vaccinated (F = 1) would be expressed in the sufficient-component cause model as causation of the disease by not getting vaccinated (F = 0). This depiction is unproblematic because, once both sides of a causal contrast have been specified, causation and prevention are merely two sides of the same coin.

Sheps (1958) once asked, "Shall we count the living or the dead?" Death is an event, but survival is not. Hence, to use the sufficient-component cause model, we must count the dead. This model restriction can have substantive implications. For instance, some measures and formulas approximate others only when the outcome is rare. When survival is rare, death is common. In that case, use of the sufficient-component cause model to inform the analysis will prevent us from taking advantage of the rare-outcome approximations.

Similarly, etiologies of adverse health outcomes that are conditions or states, but not events, must be depicted under the sufficient-cause model by reversing the coding of the outcome. Consider spina bifida, which is the failure of the neural tube to close fully during gestation. There is no point in time at which spina bifida may be said to have occurred. It would be awkward to define the "incidence time" of spina bifida as the gestational age at which complete neural tube closure ordinarily occurs. The sufficient-component cause model would be better suited in this case to defining the event of complete closure (no spina bifida) as the outcome and to view conditions, events, and characteristics that prevent this beneficial event as the causes of the adverse condition of spina bifida.

PROBABILITY, RISK, AND CAUSES

In everyday language, "risk" is often used as a synonym for probability. It is also commonly used as a synonym for "hazard," as in, "Living near a nuclear power plant is a risk you should avoid." Unfortunately, in epidemiologic parlance, even in the scholarly literature, "risk" is frequently used for many distinct concepts: rate, rate ratio, risk ratio, incidence odds, prevalence, etc. The more

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specific, and therefore more useful, definition of *risk* is "probability of an event during a specified period of time."

The term *probability* has multiple meanings. One is that it is the relative frequency of an event. Another is that probability is the tendency, or propensity, of an entity to produce an event. A third meaning is that probability measures someone's degree of certainty that an event will occur. When one says "the probability of death in vehicular accidents when traveling >120 km/h is high," one means that the proportion of accidents that end with deaths is higher when they involve vehicles traveling >120 km/h than when they involve vehicles traveling at lower speeds (frequency usage), that high-speed accidents have a greater tendency than lower-speed accidents to result in deaths (propensity usage), or that the speaker is more certain that a death will occur in a high-speed accident than in a lower-speed accident (certainty usage).

The frequency usage of "probability" and "risk," unlike the propensity and certainty usages, admits no meaning to the notion of "risk" for an individual beyond the relative frequency of 100% if the event occurs and 0% if it does not. This restriction of individual risks to 0 or 1 can only be relaxed to allow values in between by reinterpreting such statements as the frequency with which the outcome would be seen upon random sampling from a very large population of individuals deemed to be "like" the individual in some way (e.g., of the same age, sex, and smoking history). If one accepts this interpretation, whether any actual sampling has been conducted or not, the notion of individual risk is replaced by the notion of the frequency of the event in question in the large population from which the individual was sampled. With this view of risk, a risk will change according to how we group individuals together to evaluate frequencies. Subjective judgment will inevitably enter into the picture in deciding which characteristics to use for grouping. For instance, should tomato consumption be taken into account in defining the class of men who are "like" a given man for purposes of determining his risk of a diagnosis of prostate cancer between his 60th and 70th birthdays? If so, which study or meta-analysis should be used to factor in this piece of information?

Unless we have found a set of conditions and events in which the disease does not occur at all, it is always a reasonable working hypothesis that, no matter how much is known about the etiology of a disease, some causal components remain unknown. We may be inclined to assign an equal risk to all individuals whose status for some components is known and identical. We may say, for example, that men who are heavy cigarette smokers have approximately a 10% lifetime risk of developing lung cancer. Some interpret this statement to mean that all men would be subject to a 10% probability of lung cancer if they were to become heavy smokers, as if the occurrence of lung cancer, aside from smoking, were purely a matter of chance. This view is untenable. A probability may be 10% conditional on one piece of information and higher or lower than 10% if we condition on other relevant information as well. For instance, men who are heavy cigarette smokers and who worked for many years in occupations with historically high levels of exposure to airborne asbestos fibers would be said to have a lifetime lung cancer risk appreciably higher than 10%.

Regardless of whether we interpret probability as relative frequency or degree of certainty, the assignment of equal risks merely reflects the particular grouping. In our ignorance, the best we can do in assessing risk is to classify people according to measured risk indicators and then assign the average risk observed within a class to persons within the class. As knowledge or specification of additional risk indicators expands, the risk estimates assigned to people will depart from average according to the presence or absence of other factors that predict the outcome.

STRENGTH OF EFFECTS

The causal model exemplified by Figure 2–2 can facilitate an understanding of some key concepts such as *strength of effect* and *interaction*. As an illustration of strength of effect, Table 2–1 displays the frequency of the eight possible patterns for exposure to A, B, and E in two hypothetical populations. Now the pie charts in Figure 2–2 depict classes of mechanisms. The first one, for instance, represents all sufficient causes that, no matter what other component causes they may contain, have in common the fact that they contain A=0 and B=1. The constituents of U_1 may, and ordinarily would, differ from individual to individual. For simplification, we shall suppose, rather unrealistically, that U_1 , U_2 , and U_3 are always present or have always occured for everyone and Figure 2–2 represents all the sufficient causes.

TABLE 2-1

Exposure Frequencies and Individual Risks in Two Hypothetical Populations According to the Possible Combinations of the Three Specified Component Causes in Fig. 2–1

В	_			Frequency of Exposure Pattern	
D	E	Sufficient Cause Completed	Risk	Population 1	Population 2
1	1	III	1	900	100
1	0	None	0	900	100
0	1	None	0	100	900
0	0	None	0	100	900
1	1	I, II, or III	1	100	900
1	0	ľ	1	100	900
0	1	II	1	900	100
0	0	none	0	900	100
	0 1 1 0	0 1 0 0 1 1 1 1 1 0 0 1 1	1 0 None 0 1 None 0 0 None 1 1 I, II, or III 1 0 I 0 1 II	1 0 None 0 0 1 None 0 0 0 None 0 1 1 I, II, or III 1 1 0 I 1 0 1 II 1	1 0 None 0 900 0 1 None 0 100 0 0 None 0 100 1 1 1, II, or III 1 100 1 0 I 1 100 0 1 II 1 900

Under these assumptions, the response of each individual to the exposure pattern in a given row can be found in the response column. The response here is the risk of developing a disease over a specified time period that is the same for all individuals. For simplification, a deterministic model of risk is employed, such that individual risks can equal only the value 0 or 1, and no values in between. A stochastic model of individual risk would relax this restriction and allow individual risks to lie between 0 and 1.

The proportion getting disease, or incidence proportion, in any subpopulation in Table 2–1 can be found by summing the number of persons at each exposure pattern with an individual risk of 1 and dividing this total by the subpopulation size. For example, if exposure A is not considered (e.g., if it were not measured), the pattern of incidence proportions in population 1 would be those in Table 2–2.

As an example of how the proportions in Table 2–2 were calculated, let us review how the incidence proportion among persons in population 1 with B=1 and E=0 was calculated: There were 900 persons with A=1, B=1, and E=0, none of whom became cases because there are no sufficient causes that can culminate in the occurrence of the disease over the study period in persons with this combination of exposure conditions. (There are two sufficient causes that contain B=1 as a component cause, but one of them contains the component cause A=0 and the other contains the component cause E=1. The presence of E=1 or E=0 blocks these etiologic mechanisms.) There were 100 persons with E=1, and E=1, and E=1, all of whom became cases because they all had E=1, the set of causal complements for the class of sufficient causes containing E=10 and

TABLE 2-2

Incidence Proportions (IP) for Combinations of Component Causes B and E in Hypothetical Population 1, Assuming That Component Cause A Is Unmeasured

	B = 1, E = 1	B = 1, E = 0	B = 0, E = 1	B=0, E=0
Cases	1,000	100	900	0
Total	1,000	1,000	1,000	1,000
IP	1.00	0.10	0.90	0.00

TABLE 2-3

Incidence Proportions (IP) for Combinations of Component Causes B and E in Hypothetical Population 2, Assuming That Component Cause A Is Unmeasured

	B = 1, E = 1	B = 1, E = 0	B = 0, E = 1	B=0, E=0
Cases	1,000	900	100	0
Total	1,000	1,000	1,000	1,000
IP	1.00	0.90	0.10	0.00

B = 1. Thus, among all 1,000 persons with B = 1 and E = 0, there were 100 cases, for an incidence proportion of 0.10.

If we were to measure strength of effect by the difference of the incidence proportions, it is evident from Table 2–2 that for population 1, E=1 has a much stronger effect than B=1, because E=1 increases the incidence proportion by 0.9 (in both levels of B), whereas B=1 increases the incidence proportion by only 0.1 (in both levels of E). Table 2–3 shows the analogous results for population 2. Although the members of this population have exactly the same causal mechanisms operating within them as do the members of population 1, the relative strengths of causative factors E=1 and B=1 are reversed, again using the incidence proportion difference as the measure of strength. B=1 now has a much stronger effect on the incidence proportion than E=1, despite the fact that A, B, and E have no association with one another in either population, and their index levels (A = 1, B = 1 and E = 1) and reference levels (A = 0, B = 0, and E = 0) are each present or have occurred in exactly half of each population.

The overall difference of incidence proportions contrasting E=1 with E=0 is (1,900/2,000)-(100/2,000)=0.9 in population 1 and (1,100/2,000)-(900/2,000)=0.1 in population 2. The key difference between populations 1 and 2 is the difference in the prevalence of the conditions under which E=1 acts to increase risk: that is, the presence of A=0 or B=1, but not both. (When A=0 and B=1, E=1 completes all three sufficient causes in Figure 2–2; it thus does not increase anyone's risk, although it may well shorten the time to the outcome.) The prevalence of the condition, "A=0 or B=1 but not both" is 1,800/2,000=90% in both levels of E=1 in population 1. In population 2, this prevalence is only 200/2,000=10% in both levels of E=1 to increase risk explains the difference in the strength of the effect of E=1 as measured by the difference in incidence proportions.

As noted above, the set of all other component causes in all sufficient causes in which a causal factor participates is called the *causal complement* of the factor. Thus, A=0, B=1, U_2 , and U_3 make up the causal complement of E=1 in the above example. This example shows that the strength of a factor's effect on the occurrence of a disease in a population, measured as the absolute difference in incidence proportions, depends on the prevalence of its causal complement. This dependence has nothing to do with the etiologic mechanism of the component's action, because the component is an equal partner in each mechanism in which it appears. Nevertheless, a factor will appear to have a strong effect, as measured by the difference of proportions getting disease, if its causal complement is common. Conversely, a factor with a rare causal complement will appear to have a weak effect.

If strength of effect is measured by the ratio of proportions getting disease, as opposed to the difference, then strength depends on more than a factor's causal complement. In particular, it depends additionally on how common or rare the components are of sufficient causes in which the specified causal factor does *not* play a role. In this example, given the ubiquity of U_1 , the effect of E=1 measured in ratio terms depends on the prevalence of E=1's causal complement and on the prevalence of the conjunction of E=1 and E=1. If many people have both E=1 and E=1, the "baseline" incidence proportion (i.e., the proportion of not-E=10 or "unexposed" persons getting disease) will be high and the proportion getting disease due to E=11.

people have both A=0 and B=1, the baseline incidence proportion will be low and the proportion getting disease due to E=1 will be comparatively high. Thus, strength of effect measured by the incidence proportion ratio depends on more conditions than does strength of effect measured by the incidence proportion difference.

Regardless of how strength of a causal factor's effect is measured, the public health significance of that effect does not imply a corresponding degree of etiologic significance. Each component cause in a given sufficient cause has the same etiologic significance. Given a specific causal mechanism, any of the component causes can have strong or weak effects using either the difference or ratio measure. The actual identities of the components of a sufficient cause are part of the mechanics of causation, whereas the strength of a factor's effect depends on the time-specific distribution of its causal complement (if strength is measured in absolute terms) plus the distribution of the components of all sufficient causes in which the factor does not play a role (if strength is measured in relative terms). Over a span of time, the strength of the effect of a given factor on disease occurrence may change because the prevalence of its causal complement in various mechanisms may also change, even if the causal mechanisms in which the factor and its cofactors act remain unchanged.

INTERACTION AMONG CAUSES

Two component causes acting in the same sufficient cause may be defined as *interacting causally* to produce disease. This definition leaves open many possible mechanisms for the interaction, including those in which two components interact in a direct physical fashion (e.g., two drugs that react to form a toxic by-product) and those in which one component (the *initiator* of the pair) alters a substrate so that the other component (the *promoter* of the pair) can act. Nonetheless, it excludes any situation in which one component E is merely a cause of another component F, with no effect of E on disease except through the component F it causes.

Acting in the same sufficient cause is not the same as one component cause acting to produce a second component cause, and then the second component going on to produce the disease (Robins and Greenland 1992, Kaufman et al., 2004). As an example of the distinction, if cigarette smoking (vs. never smoking) is a component cause of atherosclerosis, and atherosclerosis (vs. no atherosclerosis) causes myocardial infarction, both smoking and atherosclerosis would be component causes (cofactors) in certain sufficient causes of myocardial infarction. They would not necessarily appear in the same sufficient cause. Rather, for a sufficient cause involving atherosclerosis as a component cause, there would be another sufficient cause in which the atherosclerosis component cause was replaced by all the component causes that brought about the atherosclerosis, including smoking. Thus, a sequential causal relation between smoking and atherosclerosis would not be enough for them to interact synergistically in the etiology of myocardial infarction, in the sufficient-cause sense. Instead, the causal sequence means that smoking can act indirectly, through atherosclerosis, to bring about myocardial infarction.

Now suppose that, perhaps in addition to the above mechanism, smoking reduces clotting time and thus causes thrombi that block the coronary arteries if they are narrowed by atherosclerosis. This mechanism would be represented by a sufficient cause containing both smoking and atherosclerosis as components and thus would constitute a synergistic interaction between smoking and atherosclerosis in causing myocardial infarction. The presence of this sufficient cause would not, however, tell us whether smoking also contributed to the myocardial infarction by causing the atherosclerosis. Thus, the basic sufficient-cause model does not alert us to indirect effects (effects of some component causes mediated by other component causes in the model). Chapters 4 and 12 introduce potential-outcome and graphical models better suited to displaying indirect effects and more general sequential mechanisms, whereas Chapter 5 discusses in detail interaction as defined in the potential-outcome framework and its relation to interaction as defined in the sufficient-cause model.

PROPORTION OF DISEASE DUE TO SPECIFIC CAUSES

In Figure 2–2, assuming that the three sufficient causes in the diagram are the only ones operating, what fraction of disease is caused by E=1? E=1 is a component cause of disease in two of the sufficient-cause mechanisms, II and III, so all disease arising through either of these two mechanisms is attributable to E=1. Note that in persons with the exposure pattern A=0, B=1, E=1, all three

sufficient causes would be completed. The first of the three mechanisms to be completed would be the one that actually produces a given case. If the first one completed is mechanism II or III, the case would be causally attributable to E=1. If mechanism I is the first one to be completed, however, E=1 would not be part of the sufficient cause producing that case. Without knowing the completion times of the three mechanisms, among persons with the exposure pattern A=0, B=1, E=1 we cannot tell how many of the 100 cases in population 1 or the 900 cases in population 2 are etiologically attributable to E=1.

Each of the cases that is etiologically attributable to E=1 can also be attributed to the other component causes in the causal mechanisms in which E=1 acts. Each component cause interacts with its complementary factors to produce disease, so each case of disease can be attributed to every component cause in the completed sufficient cause. Note, though, that the attributable fractions added across component causes of the same disease do not sum to 1, although there is a mistaken tendency to think that they do. To illustrate the mistake in this tendency, note that a necessary component cause appears in every completed sufficient cause of disease, and so by itself has an attributable fraction of 1, without counting the attributable fractions for other component causes. Because every case of disease can be attributed to every component cause in its causal mechanism, attributable fractions for different component causes will generally sum to more than 1, and there is no upper limit for this sum.

A recent debate regarding the proportion of risk factors for coronary heart disease attributable to particular component causes illustrates the type of errors in inference that can arise when the sum is thought to be restricted to 1. The debate centers around whether the proportion of coronary heart disease attributable to high blood cholesterol, high blood pressure, and cigarette smoking equals 75% or "only 50%" (Magnus and Beaglehole, 2001). If the former, then some have argued that the search for additional causes would be of limited utility (Beaglehole and Magnus, 2002), because only 25% of cases "remain to be explained." By assuming that the proportion explained by yet unknown component causes cannot exceed 25%, those who support this contention fail to recognize that cases caused by a sufficient cause that contains any subset of the three named causes might also contain unknown component causes. Cases stemming from sufficient causes with this overlapping set of component causes could be prevented by interventions targeting the three named causes, or by interventions targeting the yet unknown causes when they become known. The latter interventions could reduce the disease burden by much more than 25%.

As another example, in a cohort of cigarette smokers exposed to arsenic by working in a smelter, an estimated 75% of the lung cancer rate was attributable to their work environment and an estimated 65% was attributable to their smoking (Pinto et al., 1978; Hertz-Picciotto et al., 1992). There is no problem with such figures, which merely reflect the multifactorial etiology of disease. So, too, with coronary heart disease; if 75% of that disease is attributable to high blood cholesterol, high blood pressure, and cigarette smoking, 100% of it can still be attributable to other causes, known, suspected, and yet to be discovered. Some of these causes will participate in the same causal mechanisms as high blood cholesterol, high blood pressure, and cigarette smoking. Beaglehole and Magnus were correct in thinking that if the three specified component causes combine to explain 75% of cardiovascular disease (CVD) and we somehow eliminated them, there would be only 25% of CVD cases remaining. But until that 75% is eliminated, any newly discovered component could cause up to 100% of the CVD we currently have.

The notion that interventions targeting high blood cholesterol, high blood pressure, and cigarette smoking could eliminate 75% of coronary heart disease is unrealistic given currently available intervention strategies. Although progress can be made to reduce the effect of these risk factors, it is unlikely that any of them could be completely eradicated from any large population in the near term. Estimates of the public health effect of eliminating diseases themselves as causes of death (Murray et al., 2002) are even further removed from reality, because they fail to account for all the effects of interventions required to achieve the disease elimination, including unanticipated side effects (Greenland, 2002a, 2005a).

The debate about coronary heart disease attribution to component causes is reminiscent of an earlier debate regarding causes of cancer. In their widely cited work, *The Causes of Cancer*, Doll and Peto (1981, Table 20) created a table giving their estimates of the fraction of all cancers caused by various agents. The fractions summed to nearly 100%. Although the authors acknowledged that any case could be caused by more than one agent (which means that, given enough agents, the attributable

fractions would sum to far more than 100%), they referred to this situation as a "difficulty" and an "anomaly" that they chose to ignore. Subsequently, one of the authors acknowledged that the attributable fraction could sum to greater than 100% (Peto, 1985). It is neither a difficulty nor an anomaly nor something we can safely ignore, but simply a consequence of the fact that no event has a single agent as the cause. The fraction of disease that can be attributed to known causes will grow without bound as more causes are discovered. Only the fraction of disease attributable to a single component cause cannot exceed 100%.

In a similar vein, much publicity attended the pronouncement in 1960 that as much as 90% of cancer is environmentally caused (Higginson, 1960). Here, "environment" was thought of as representing all nongenetic component causes, and thus included not only the physical environment, but also the social environment and all individual human behavior that is not genetically determined. Hence, environmental component causes must be present to some extent in every sufficient cause of a disease. Thus, Higginson's estimate of 90% was an underestimate.

One can also show that 100% of any disease is inherited, even when environmental factors are component causes. MacMahon (1968) cited the example given by Hogben (1933) of yellow shanks, a trait occurring in certain genetic strains of fowl fed on yellow corn. Both a particular set of genes and a yellow-corn diet are necessary to produce yellow shanks. A farmer with several strains of fowl who feeds them all only yellow corn would consider yellow shanks to be a genetic condition, because only one strain would get yellow shanks, despite all strains getting the same diet. A different farmer who owned only the strain liable to get yellow shanks but who fed some of the birds yellow corn and others white corn would consider yellow shanks to be an environmentally determined condition because it depends on diet. In humans, the mental retardation caused by phenylketonuria is considered by many to be purely genetic. This retardation can, however, be successfully prevented by dietary intervention, which demonstrates the presence of an environmental cause. In reality, yellow shanks, phenylketonuria, and other diseases and conditions are determined by an interaction of genes and environment. It makes no sense to allocate a portion of the causation to either genes or environment separately when both may act together in sufficient causes.

Nonetheless, many researchers have compared disease occurrence in identical and nonidentical twins to estimate the fraction of disease that is inherited. These twin-study and other heritability indices assess only the relative role of environmental and genetic causes of disease in a particular setting. For example, some genetic causes may be necessary components of every causal mechanism. If everyone in a population has an identical set of the genes that cause disease, however, their effect is not included in heritability indices, despite the fact that the genes are causes of the disease. The two farmers in the preceding example would offer very different values for the heritability of yellow shanks, despite the fact that the condition is always 100% dependent on having certain genes.

Every case of every disease has some environmental and some genetic component causes, and therefore every case can be attributed both to genes and to environment. No paradox exists as long as it is understood that the fractions of disease attributable to genes and to environment overlap with one another. Thus, debates over what proportion of all occurrences of a disease are genetic and what proportion are environmental, inasmuch as these debates assume that the shares must add up to 100%, are fallacious and distracting from more worthwhile pursuits.

On an even more general level, the question of whether a given disease does or does not have a "multifactorial etiology" can be answered once and for all in the affirmative. All diseases have multifactorial etiologies. It is therefore completely unremarkable for a given disease to have such an etiology, and no time or money should be spent on research trying to answer the question of whether a particular disease does or does not have a multifactorial etiology. They all do. The job of etiologic research is to identify components of those etiologies.

INDUCTION PERIOD

Pie-chart diagrams of sufficient causes and their components such as those in Figure 2–2 are not well suited to provide a model for conceptualizing the *induction period*, which may be defined as the period of time from causal action until disease initiation. There is no way to tell from a pie-chart diagram of a sufficient cause which components affect each other, which components must come before or after others, for which components the temporal order is irrelevant, etc. The crucial

information on temporal ordering must come in a separate description of the interrelations among the components of a sufficient cause.

If, in sufficient cause I, the sequence of action of the specified component causes must be A=0, B=1 and we are studying the effect of A=0, which (let us assume) acts at a narrowly defined point in time, we do not observe the occurrence of disease immediately after A=0 occurs. Disease occurs only after the sequence is completed, so there will be a delay while B=1 occurs (along with components of the set U_1 that are not present or that have not occured when A=0 occurs). When B=1 acts, if it is the last of all the component causes (including those in the set of unspecified conditions and events represented by U_1), disease occurs. The interval between the action of B=1 and the disease occurrence is the induction time for the effect of B=1 in sufficient cause I.

In the example given earlier of an equilibrium disorder leading to a later fall and hip injury, the induction time between the start of the equilibrium disorder and the later hip injury might be long, if the equilibrium disorder is caused by an old head injury, or short, if the disorder is caused by inebriation. In the latter case, it could even be instantaneous, if we define it as blood alcohol greater than a certain level. This latter possibility illustrates an important general point: Component causes that do not change with time, as opposed to events, all have induction times of zero.

Defining an induction period of interest is tantamount to specifying the characteristics of the component causes of interest. A clear example of a lengthy induction time is the cause–effect relation between exposure of a female fetus to diethylstilbestrol (DES) and the subsequent development of adenocarcinoma of the vagina. The cancer is usually diagnosed between ages 15 and 30 years. Because the causal exposure to DES occurs early in pregnancy, there is an induction time of about 15 to 30 years for the carcinogenic action of DES. During this time, other causes presumably are operating; some evidence suggests that hormonal action during adolescence may be part of the mechanism (Rothman, 1981).

It is incorrect to characterize a disease itself as having a lengthy or brief induction period. The induction time can be conceptualized only in relation to a specific component cause operating in a specific sufficient cause. Thus, we say that the induction time relating DES to clear-cell carcinoma of the vagina is 15 to 30 years, but we should not say that 15 to 30 years is the induction time for clear-cell carcinoma in general. Because each component cause in any causal mechanism can act at a time different from the other component causes, each can have its own induction time. For the component cause that acts last, the induction time equals zero. If another component cause of clear-cell carcinoma of the vagina that acts during adolescence were identified, it would have a much shorter induction time for its carcinogenic action than DES. Thus, induction time characterizes a specific cause—effect pair rather than just the effect.

In carcinogenesis, the terms *initiator* and *promotor* have been used to refer to some of the component causes of cancer that act early and late, respectively, in the causal mechanism. Cancer itself has often been characterized as a disease process with a long induction time. This characterization is a misconception, however, because any late-acting component in the causal process, such as a promotor, will have a short induction time. Indeed, by definition, the induction time will always be zero for at least one component cause, the last to act. The mistaken view that diseases, as opposed to cause—disease relationships, have long or short induction periods can have important implications for research. For instance, the view of adult cancers as "diseases of long latency" may induce some researchers to ignore evidence of etiologic effects occurring relatively late in the processes that culminate in clinically diagnosed cancers. At the other extreme, the routine disregard for exposures occurring in the first decade or two in studies of occupational carcinogenesis, as a major example, may well have inhibited the discovery of occupational causes with very long induction periods.

Disease, once initiated, will not necessarily be apparent. The time interval between irreversible disease occurrence and detection has been termed the *latent period* (Rothman, 1981), although others have used this term interchangeably with induction period. Still others use *latent period* to mean the total time between causal action and disease detection. We use *induction period* to describe the time from causal action to irreversible disease occurrence and *latent period* to mean the time from disease occurrence to disease detection. The latent period can sometimes be reduced by improved methods of disease detection. The induction period, on the other hand, cannot be reduced by early detection of disease, because disease occurrence marks the end of the induction period. Earlier detection of disease, however, may reduce the apparent induction period (the time between causal action and disease detection), because the time when disease is detected, as a practical matter, is

usually used to mark the time of disease occurrence. Thus, diseases such as slow-growing cancers may appear to have long induction periods with respect to many causes because they have long latent periods. The latent period, unlike the induction period, is a characteristic of the disease and the detection effort applied to the person with the disease.

Although it is not possible to reduce the induction period proper by earlier detection of disease, it may be possible to observe intermediate stages of a causal mechanism. The increased interest in biomarkers such as DNA adducts is an example of attempting to focus on causes more proximal to the disease occurrence or on effects more proximal to cause occurrence. Such biomarkers may nonetheless reflect the effects of earlier-acting agents on the person.

Some agents may have a causal action by shortening the induction time of other agents. Suppose that exposure to factor X=1 leads to epilepsy after an interval of 10 years, on average. It may be that exposure to a drug, Z=1, would shorten this interval to 2 years. Is Z=1 acting as a catalyst, or as a cause, of epilepsy? The answer is both: A catalyst is a cause. Without Z=1, the occurrence of epilepsy comes 8 years later than it comes with Z=1, so we can say that Z=1 causes the onset of the early epilepsy. It is not sufficient to argue that the epilepsy would have occurred anyway. First, it would not have occurred at that time, and the time of occurrence is part of our definition of an event. Second, epilepsy will occur later only if the individual survives an additional 8 years, which is not certain. Not only does agent Z=1 determine when the epilepsy occurs, it can also determine whether it occurs. Thus, we should call any agent that acts as a catalyst of a causal mechanism, speeding up an induction period for other agents, a cause in its own right. Similarly, any agent that postpones the onset of an event, drawing out the induction period for another agent, is a preventive. It should not be too surprising to equate postponement to prevention: We routinely use such an equation when we employ the euphemism that we "prevent" death, which actually can only be postponed. What we prevent is death at a given time, in favor of death at a later time.

SCOPE OF THE MODEL

The main utility of this model of sufficient causes and their components lies in its ability to provide a general but practical conceptual framework for causal problems. The attempt to make the proportion of disease attributable to various component causes add to 100% is an example of a fallacy that is exposed by the model (although MacMahon and others were able to invoke yellow shanks and phenylketonuria to expose that fallacy long before the sufficient-component cause model was formally described [MacMahon and Pugh, 1967, 1970]). The model makes it clear that, because of interactions, there is no upper limit to the sum of these proportions. As we shall see in Chapter 5, the epidemiologic evaluation of interactions themselves can be clarified, to some extent, with the help of the model.

Although the model appears to deal qualitatively with the action of component causes, it can be extended to account for dose dependence by postulating a set of sufficient causes, each of which contains as a component a different dose of the agent in question. Small doses might require a larger or rarer set of complementary causes to complete a sufficient cause than that required by large doses (Rothman, 1976a), in which case it is particularly important to specify both sides of the causal contrast. In this way, the model can account for the phenomenon of a shorter induction period accompanying larger doses of exposure, because a smaller set of complementary components would be needed to complete the sufficient cause.

Those who believe that chance must play a role in any complex mechanism might object to the intricacy of this seemingly deterministic model. A probabilistic (stochastic) model could be invoked to describe a dose–response relation, for example, without the need for a multitude of different causal mechanisms. The model would simply relate the dose of the exposure to the probability of the effect occurring. For those who believe that virtually all events contain some element of chance, deterministic causal models may seem to misrepresent the indeterminism of the real world. However, the deterministic model presented here can accommodate "chance"; one way might be to view chance, or at least some part of the variability that we call "chance," as the result of deterministic events that are beyond the current limits of knowledge or observability.

For example, the outcome of a flip of a coin is usually considered a chance event. In classical mechanics, however, the outcome can in theory be determined completely by the application of physical laws and a sufficient description of the starting conditions. To put it in terms more familiar

to epidemiologists, consider the explanation for why an individual gets lung cancer. One hundred years ago, when little was known about the etiology of lung cancer; a scientist might have said that it was a matter of chance. Nowadays, we might say that the risk depends on how much the individual smokes, how much asbestos and radon the individual has been exposed to, and so on. Nonetheless, recognizing this dependence moves the line of ignorance; it does not eliminate it. One can still ask what determines whether an individual who has smoked a specific amount and has a specified amount of exposure to all the other known risk factors will get lung cancer. Some will get lung cancer and some will not, and if all known risk factors are already taken into account, what is left we might still describe as chance. True, we can explain much more of the variability in lung cancer occurrence nowadays than we formerly could by taking into account factors known to cause it, but at the limits of our knowledge, we still ascribe the remaining variability to what we call chance. In this view, chance is seen as a catchall term for our ignorance about causal explanations.

We have so far ignored more subtle considerations of sources of unpredictability in events, such as chaotic behavior (in which even the slightest uncertainty about initial conditions leads to vast uncertainty about outcomes) and quantum-mechanical uncertainty. In each of these situations, a random (stochastic) model component may be essential for any useful modeling effort. Such components can also be introduced in the above conceptual model by treating unmeasured component causes in the model as random events, so that the causal model based on components of sufficient causes can have random elements. An example is treatment assignment in randomized clinical trials (Poole 2001a).

OTHER MODELS OF CAUSATION

The sufficient-component cause model is only one of several models of causation that may be useful for gaining insight about epidemiologic concepts (Greenland and Brumback, 2002; Greenland, 2004a). It portrays qualitative causal mechanisms within members of a population, so its fundamental unit of analysis is the causal mechanism rather than a person. Many different sets of mechanisms can lead to the same pattern of disease within a population, so the sufficient-component cause model involves specification of details that are beyond the scope of epidemiologic data. Also, it does not incorporate elements reflecting population distributions of factors or causal sequences, which are crucial to understanding confounding and other biases.

Other models of causation, such as potential-outcome (counterfactual) models and graphical models, provide direct representations of epidemiologic concepts such as confounding and other biases, and can be applied at mechanistic, individual, or population levels of analysis. Potential-outcome models (Chapters 4 and 5) specify in detail what would happen to individuals or populations under alternative possible patterns of interventions or exposures, and also bring to the fore problems in operationally defining causes (Greenland, 2002a, 2005a; Hernán, 2005). Graphical models (Chapter 12) display broad qualitative assumptions about causal directions and independencies. Both types of model have close relationships to the structural-equations models that are popular in the social sciences (Pearl, 2000; Greenland and Brumback, 2002), and both can be subsumed under a general theory of longitudinal causality (Robins, 1997).

PHILOSOPHY OF SCIENTIFIC INFERENCE

Causal inference may be viewed as a special case of the more general process of scientific reasoning. The literature on this topic is too vast for us to review thoroughly, but we will provide a brief overview of certain points relevant to epidemiology, at the risk of some oversimplification.

INDUCTIVISM

Modern science began to emerge around the 16th and 17th centuries, when the knowledge demands of emerging technologies (such as artillery and transoceanic navigation) stimulated inquiry into the origins of knowledge. An early codification of the scientific method was Francis Bacon's *Novum Organum*, which, in 1620, presented an inductivist view of science. In this philosophy, scientific reasoning is said to depend on making generalizations, or inductions, from observations to general laws of nature; the observations are said to induce the formulation of a natural law in the mind of

the scientist. Thus, an inductivist would have said that Jenner's observation of lack of smallpox among milkmaids induced in Jenner's mind the theory that cowpox (common among milkmaids) conferred immunity to smallpox. Inductivist philosophy reached a pinnacle of sorts in the canons of John Stuart Mill (1862), which evolved into inferential criteria that are still in use today.

Inductivist philosophy was a great step forward from the medieval scholasticism that preceded it, for at least it demanded that a scientist make careful observations of people and nature rather than appeal to faith, ancient texts, or authorities. Nonetheless, in the 18th century the Scottish philosopher David Hume described a disturbing deficiency in inductivism. An inductive argument carried no logical force; instead, such an argument represented nothing more than an *assumption* that certain events would in the future follow the same pattern as they had in the past. Thus, to argue that cowpox caused immunity to smallpox because no one got smallpox after having cowpox corresponded to an unjustified assumption that the pattern observed to date (no smallpox after cowpox) would continue into the future. Hume pointed out that, even for the most reasonable-sounding of such assumptions, there was no logical necessity behind the inductive argument.

Of central concern to Hume (1739) was the issue of causal inference and failure of induction to provide a foundation for it:

Thus not only our reason fails us in the discovery of the ultimate connexion of causes and effects, but even after experience has inform'd us of their constant conjunction, 'tis impossible for us to satisfy ourselves by our reason, why we shou'd extend that experience beyond those particular instances, which have fallen under our observation. We suppose, but are never able to prove, that there must be a resemblance betwixt those objects, of which we have had experience, and those which lie beyond the reach of our discovery.

In other words, no number of repetitions of a particular sequence of events, such as the appearance of a light after flipping a switch, can prove a causal connection between the action of the switch and the turning on of the light. No matter how many times the light comes on after the switch has been pressed, the possibility of coincidental occurrence cannot be ruled out. Hume pointed out that observers cannot perceive causal connections, but only a series of events. Bertrand Russell (1945) illustrated this point with the example of two accurate clocks that perpetually chime on the hour, with one keeping time slightly ahead of the other. Although one invariably chimes before the other, there is no direct causal connection from one to the other. Thus, assigning a causal interpretation to the pattern of events cannot be a logical extension of our observations alone, because the events might be occurring together only because of a shared earlier cause, or because of some systematic error in the observations.

Causal inference based on mere association of events constitutes a logical fallacy known as *post hoc ergo propter hoc* (Latin for "after this therefore on account of this"). This fallacy is exemplified by the inference that the crowing of a rooster is necessary for the sun to rise because sunrise is always preceded by the crowing.

The post hoc fallacy is a special case of a more general logical fallacy known as the fallacy of affirming the consequent. This fallacy of confirmation takes the following general form: "We know that if H is true, B must be true; and we know that B is true; therefore H must be true." This fallacy is used routinely by scientists in interpreting data. It is used, for example, when one argues as follows: "If sewer service causes heart disease, then heart disease rates should be highest where sewer service is available; heart disease rates are indeed highest where sewer service is available; therefore, sewer service causes heart disease." Here, H is the hypothesis "sewer service causes heart disease" and B is the observation "heart disease rates are highest where sewer service is available." The argument is logically unsound, as demonstrated by the fact that we can imagine many ways in which the premises could be true but the conclusion false; for example, economic development could lead to both sewer service and elevated heart disease rates, without any effect of sewer service on heart disease. In this case, however, we also know that one of the premises is not true—specifically, the premise, "If H is true, B must be true." This particular form of the fallacy exemplifies the problem of confounding, which we will discuss in detail in later chapters.

Bertrand Russell (1945) satirized the fallacy this way:

'If p, then q; now q is true; therefore p is true.' E.g., 'If pigs have wings, then some winged animals are good to eat; now some winged animals are good to eat; therefore pigs have wings.' This form of inference is called 'scientific method.'

Section I • Basic Concepts

REFUTATIONISM

Russell was not alone in his lament of the illogicality of scientific reasoning as ordinarily practiced. Many philosophers and scientists from Hume's time forward attempted to set out a firm logical basis for scientific reasoning.

In the 1920s, most notable among these was the school of logical positivists, who sought a logic for science that could lead inevitably to correct scientific conclusions, in much the way rigorous logic can lead inevitably to correct conclusions in mathematics. Other philosophers and scientists, however, had started to suspect that scientific hypotheses can never be proven or established as true in any logical sense. For example, a number of philosophers noted that scientific statements can only be found to be consistent with observation, but cannot be proven or disproven in any "airtight" logical or mathematical sense (Duhem, 1906, transl. 1954; Popper 1934, transl. 1959; Quine, 1951). This fact is sometimes called the problem of *nonidentification* or *underdetermination* of theories by observations (Curd and Cover, 1998). In particular, available observations are always consistent with several hypotheses that themselves are mutually inconsistent, which explains why (as Hume noted) scientific theories cannot be logically proven. In particular, consistency between a hypothesis and observations is no proof of the hypothesis, because we can always invent alternative hypotheses that are just as consistent with the observations.

In contrast, a valid observation that is inconsistent with a hypothesis implies that the hypothesis as stated is false and so refutes the hypothesis. If you wring the rooster's neck before it crows and the sun still rises, you have disproved that the rooster's crowing is a necessary cause of sunrise. Or consider a hypothetical research program to learn the boiling point of water (Magee, 1985). A scientist who boils water in an open flask and repeatedly measures the boiling point at 100°C will never, no matter how many confirmatory repetitions are involved, prove that 100°C is always the boiling point. On the other hand, merely one attempt to boil the water in a closed flask or at high altitude will refute the proposition that water always boils at 100°C.

According to Popper, science advances by a process of elimination that he called "conjecture and refutation." Scientists form hypotheses based on intuition, conjecture, and previous experience. Good scientists use deductive logic to infer predictions from the hypothesis and then compare observations with the predictions. Hypotheses whose predictions agree with observations are confirmed (Popper used the term "corroborated") only in the sense that they can continue to be used as explanations of natural phenomena. At any time, however, they may be refuted by further observations and might be replaced by other hypotheses that are more consistent with the observations. This view of scientific inference is sometimes called *refutationism* or *falsificationism*. Refutationists consider induction to be a psychologic crutch: Repeated observations did not in fact induce the formulation of a natural law, but only the belief that such a law has been found. For a refutationist, only the psychologic comfort provided by induction explains why it still has advocates.

One way to rescue the concept of induction from the stigma of pure delusion is to resurrect it as a psychologic phenomenon, as Hume and Popper claimed it was, but one that plays a legitimate role in hypothesis formation. The philosophy of conjecture and refutation places no constraints on the origin of conjectures. Even delusions are permitted as hypotheses, and therefore inductively inspired hypotheses, however psychologic, are valid starting points for scientific evaluation. This concession does not admit a logical role for induction in confirming scientific hypotheses, but it allows the process of induction to play a part, along with imagination, in the scientific cycle of conjecture and refutation.

The philosophy of conjecture and refutation has profound implications for the methodology of science. The popular concept of a scientist doggedly assembling evidence to support a favorite thesis is objectionable from the standpoint of refutationist philosophy because it encourages scientists to consider their own pet theories as their intellectual property, to be confirmed, proven, and, when all the evidence is in, cast in stone and defended as natural law. Such attitudes hinder critical evaluation, interchange, and progress. The approach of conjecture and refutation, in contrast, encourages scientists to consider multiple hypotheses and to seek crucial tests that decide between competing hypotheses by falsifying one of them. Because falsification of one or more theories is the goal, there is incentive to depersonalize the theories. Criticism leveled at a theory need not be seen as criticism of the person who proposed it. It has been suggested that the reason why certain fields of science advance rapidly while others languish is that the rapidly advancing fields are propelled by scientists

who are busy constructing and testing competing hypotheses; the other fields, in contrast, "are sick by comparison, because they have forgotten the necessity for alternative hypotheses and disproof" (Platt, 1964).

The refutationist model of science has a number of valuable lessons for research conduct, especially of the need to seek alternative explanations for observations, rather than focus on the chimera of seeking scientific "proof" for some favored theory. Nonetheless, it is vulnerable to criticisms that observations (or some would say their interpretations) are themselves laden with theory (sometimes called the *Duhem-Quine thesis*; Curd and Cover, 1998). Thus, observations can never provide the sort of definitive refutations that are the hallmark of popular accounts of refutationism. For example, there may be uncontrolled and even unimagined biases that have made our refutational observations invalid; to claim refutation is to assume as true the unprovable theory that no such bias exists. In other words, not only are theories underdetermined by observations, so are refutations, which are themselves theory-laden. The net result is that logical certainty about either the truth or falsity of an internally consistent theory is impossible (Quine, 1951).

CONSENSUS AND NATURALISM

Some 20th-century philosophers of science, most notably Thomas Kuhn (1962), emphasized the role of the scientific community in judging the validity of scientific theories. These critics of the conjecture-and-refutation model suggested that the refutation of a theory involves making a choice. Every observation is itself dependent on theories. For example, observing the moons of Jupiter through a telescope seems to us like a direct observation, but only because the theory of optics on which the telescope is based is so well accepted. When confronted with a refuting observation, a scientist faces the choice of rejecting either the validity of the theory being tested or the validity of the refuting observation, which itself must be premised on scientific theories that are not certain (Haack, 2003). Observations that are falsifying instances of theories may at times be treated as "anomalies," tolerated without falsifying the theory in the hope that the anomalies may eventually be explained. An epidemiologic example is the observation that shallow-inhaling smokers had higher lung cancer rates than deep-inhaling smokers. This anomaly was eventually explained when it was noted that lung tissue higher in the lung is more susceptible to smoking-associated lung tumors, and shallowly inhaled smoke tars tend to be deposited higher in the lung (Wald, 1985).

In other instances, anomalies may lead eventually to the overthrow of current scientific doctrine, just as Newtonian mechanics was displaced (remaining only as a first-order approximation) by relativity theory. Kuhn asserted that in every branch of science the prevailing scientific viewpoint, which he termed "normal science," occasionally undergoes major shifts that amount to scientific revolutions. These revolutions signal a decision of the scientific community to discard the scientific infrastructure rather than to falsify a new hypothesis that cannot be easily grafted onto it. Kuhn and others have argued that the consensus of the scientific community determines what is considered accepted and what is considered refuted.

Kuhn's critics characterized this description of science as one of an irrational process, "a matter for mob psychology" (Lakatos, 1970). Those who believe in a rational structure for science consider Kuhn's vision to be a regrettably real description of much of what passes for scientific activity, but not prescriptive for any good science. Although many modern philosophers reject rigid demarcations and formulations for science such as refutationism, they nonetheless maintain that science is founded on reason, albeit possibly informal common sense (Haack, 2003). Others go beyond Kuhn and maintain that attempts to impose a singular rational structure or methodology on science hobbles the imagination and is a prescription for the same sort of authoritarian repression of ideas that scientists have had to face throughout history (Feyerabend, 1975 and 1993).

The philosophic debate about Kuhn's description of science hinges on whether Kuhn meant to describe only what has happened historically in science or instead what ought to happen, an issue about which Kuhn (1970) has not been completely clear:

Are Kuhn's [my] remarks about scientific development. . . to be read as descriptions or prescriptions? The answer, of course, is that they should be read in both ways at once. If I have a theory of how and why science works, it must necessarily have implications for the way in which scientists should behave if their enterprise is to flourish.

The idea that science is a sociologic process, whether considered descriptive or normative, is an interesting thesis, as is the idea that from observing how scientists work we can learn about how scientists ought to work. The latter idea has led to the development of *naturalistic* philosophy of science, or "science studies," which examines scientific developments for clues about what sort of methods scientists need and develop for successful discovery and invention (Callebaut, 1993; Giere, 1999).

Regardless of philosophical developments, we suspect that most epidemiologists (and most scientists) will continue to function as if the following classical view is correct: The ultimate goal of scientific inference is to capture some objective truths about the material world in which we live, and any theory of inference should ideally be evaluated by how well it leads us to these truths. This ideal is impossible to operationalize, however, for if we ever find any ultimate truths, we will have no way of knowing that for certain. Thus, those holding the view that scientific truth is not arbitrary nevertheless concede that our knowledge of these truths will always be tentative. For refutationists, this tentativeness has an asymmetric quality, but that asymmetry is less marked for others. We may believe that we know a theory is false because it consistently fails the tests we put it through, but our tests could be faulty, given that they involve imperfect reasoning and sense perception. Neither can we know that a theory is true, even if it passes every test we can devise, for it may fail a test that is as yet undevised.

Few, if any, would disagree that a theory of inference should be evaluated at least in part by how well it leads us to detect errors in our hypotheses and observations. There are, however, many other inferential activities besides evaluation of hypotheses, such as prediction or forecasting of events, and subsequent attempts to control events (which of course requires causal information). Statisticians rather than philosophers have more often confronted these problems in practice, so it should not be surprising that the major philosophies concerned with these problems emerged from statistics rather than philosophy.

BAYESIANISM

There is another philosophy of inference that, like most, holds an objective view of scientific truth and a view of knowledge as tentative or uncertain, but that focuses on evaluation of knowledge rather than truth. Like refutationism, the modern form of this philosophy evolved from the writings of 18th-century thinkers. The focal arguments first appeared in a pivotal essay by the Reverend Thomas Bayes (1764), and hence the philosophy is usually referred to as Bayesianism (Howson and Urbach, 1993), and it was the renowned French mathematician and scientist Pierre Simon de Laplace who first gave it an applied statistical format. Nonetheless, it did not reach a complete expression until after World War I, most notably in the writings of Ramsey (1931) and DeFinetti (1937); and, like refutationism, it did not begin to appear in epidemiology until the 1970s (e.g., Cornfield, 1976).

The central problem addressed by Bayesianism is the following: In classical logic, a deductive argument can provide no information about the truth or falsity of a scientific hypothesis unless you can be 100% certain about the truth of the premises of the argument. Consider the logical argument called *modus tollens*: "If H implies B, and B is false, then H must be false." This argument is logically valid, but the conclusion follows only on the assumptions that the premises "H implies B" and "B is false" are true statements. If these premises are statements about the physical world, we cannot possibly know them to be correct with 100% certainty, because all observations are subject to error. Furthermore, the claim that "H implies B" will often depend on its own chain of deductions, each with its own premises of which we cannot be certain.

For example, if H is "Television viewing causes homicides" and B is "Homicide rates are highest where televisions are most common," the first premise used in *modus tollens* to test the hypothesis that television viewing causes homicides will be: "If television viewing causes homicides, homicide rates are highest where televisions are most common." The validity of this premise is doubtful—after all, even if television does cause homicides, homicide rates may be low where televisions are common because of socioeconomic advantages in those areas.

Continuing to reason in this fashion, we could arrive at a more pessimistic state than even Hume imagined. Not only is induction without logical foundation, *deduction* has limited scientific utility because we cannot ensure the truth of all the premises, even if a logical argument is valid.

The Bayesian answer to this problem is partial in that it makes a severe demand on the scientist and puts a severe limitation on the results. It says roughly this: If you can assign a degree of certainty, or personal probability, to the premises of your valid argument, you may use any and all the rules of probability theory to derive a certainty for the conclusion, and this certainty will be a logically valid consequence of your original certainties. An inescapable fact is that your concluding certainty, or *posterior probability*, may depend heavily on what you used as initial certainties, or *prior probabilities*. If those initial certainties are not the same as those of a colleague, that colleague may very well assign a certainty to the conclusion different from the one you derived. With the accumulation of consistent evidence, however, the data can usually force even extremely disparate priors to converge into similar posterior probabilities.

Because the posterior probabilities emanating from a Bayesian inference depend on the person supplying the initial certainties and so may vary across individuals, the inferences are said to be subjective. This subjectivity of Bayesian inference is often mistaken for a subjective treatment of truth. Not only is such a view of Bayesianism incorrect, it is diametrically opposed to Bayesian philosophy. The Bayesian approach represents a constructive attempt to deal with the dilemma that scientific laws and facts should not be treated as known with certainty, whereas classic deductive logic yields conclusions only when some law, fact, or connection is asserted with 100% certainty.

A common criticism of Bayesian philosophy is that it diverts attention away from the classic goals of science, such as the discovery of how the world works, toward psychologic states of mind called "certainties," "subjective probabilities," or "degrees of belief" (Popper, 1959). This criticism, however, fails to recognize the importance of a scientist's state of mind in determining what theories to test and what tests to apply, the consequent influence of those states on the store of data available for inference, and the influence of the data on the states of mind.

Another reply to this criticism is that scientists already use data to influence their degrees of belief, and they are not shy about expressing those degrees of certainty. The problem is that the conventional process is informal, intuitive, and ineffable, and therefore not subject to critical scrutiny; at its worst, it often amounts to nothing more than the experts announcing that they have seen the evidence and here is how certain they are. How they reached this certainty is left unclear, or, put another way, is not "transparent." The problem is that no one, even an expert, is very good at informally and intuitively formulating certainties that predict facts and future events well (Kahneman et al., 1982; Gilovich, 1993; Piattelli-Palmarini, 1994; Gilovich et al., 2002). One reason for this problem is that biases and prior prejudices can easily creep into expert judgments. Bayesian methods force experts to "put their cards on the table" and specify explicitly the strength of their prior beliefs and why they have such beliefs, defend those specifications against arguments and evidence, and update their degrees of certainty with new evidence in ways that do not violate probability logic.

In any research context, there will be an unlimited number of hypotheses that could explain an observed phenomenon. Some argue that progress is best aided by severely testing (empirically challenging) those explanations that seem most probable in light of past research, so that short-comings of currently "received" theories can be most rapidly discovered. Indeed, much research in certain fields takes this form, as when theoretical predictions of particle mass are put to ever more precise tests in physics experiments. This process does not involve mere improved repetition of past studies. Rather, it involves tests of previously untested but important predictions of the theory. Moreover, there is an imperative to make the basis for prior beliefs criticizable and defensible. That prior probabilities can differ among persons does not mean that all such beliefs are based on the same information, nor that all are equally tenable.

Probabilities of auxiliary hypotheses are also important in study design and interpretation. Failure of a theory to pass a test can lead to rejection of the theory more rapidly when the auxiliary hypotheses on which the test depends possess high probability. This observation provides a rationale for preferring "nested" case-control studies (in which controls are selected from a roster of the source population for the cases) to "hospital-based" case-control studies (in which the controls are "selected" by the occurrence or diagnosis of one or more diseases other than the case-defining disease), because the former have fewer mechanisms for biased subject selection and hence are given a higher probability of unbiased subject selection.

Even if one disputes the above arguments, most epidemiologists desire some way of expressing the varying degrees of certainty about possible values of an effect measure in light of available data. Such expressions must inevitably be derived in the face of considerable uncertainty about

methodologic details and various events that led to the available data and can be extremely sensitive to the reasoning used in its derivation. For example, as we shall discuss at greater length in Chapter 19, conventional confidence intervals quantify only random error under often questionable assumptions and so should not be interpreted as measures of total uncertainty, particularly for nonexperimental studies. As noted earlier, most people, including scientists, reason poorly in the face of uncertainty. At the very least, subjective Bayesian philosophy provides a methodology for sound reasoning under uncertainty and, in particular, provides many warnings against being overly certain about one's conclusions (Greenland 1998a, 1988b, 2006a; see also Chapters 18 and 19).

Such warnings are echoed in refutationist philosophy. As Peter Medawar (1979) put it, "I cannot give any scientist of any age better advice than this: the intensity of the conviction that a hypothesis is true has no bearing on whether it is true or not." We would add two points. First, the intensity of conviction that a hypothesis is false has no bearing on whether it is false or not. Second, Bayesian methods do not mistake beliefs for evidence. They use evidence to modify beliefs, which scientists routinely do in any event, but often in implicit, intuitive, and incoherent ways.

IMPOSSIBILITY OF SCIENTIFIC PROOF

Vigorous debate is a characteristic of modern scientific philosophy, no less in epidemiology than in other areas (Rothman, 1988). Can divergent philosophies of science be reconciled? Haack (2003) suggested that the scientific enterprise is akin to solving a vast, collective crossword puzzle. In areas in which the evidence is tightly interlocking, there is more reason to place confidence in the answers, but in areas with scant information, the theories may be little better than informed guesses. Of the scientific method, Haack (2003) said that "there is less to the 'scientific method' than meets the eye. Is scientific inquiry categorically different from other kinds? No. Scientific inquiry is continuous with everyday empirical inquiry—only more so."

Perhaps the most important common thread that emerges from the debated philosophies is that proof is impossible in empirical science. This simple fact is especially important to observational epidemiologists, who often face the criticism that proof is impossible in epidemiology, with the implication that it is possible in other scientific disciplines. Such criticism may stem from a view that experiments are the definitive source of scientific knowledge. That view is mistaken on at least two counts. First, the nonexperimental nature of a science does not preclude impressive scientific discoveries; the myriad examples include plate tectonics, the evolution of species, planets orbiting other stars, and the effects of cigarette smoking on human health. Even when they are possible, experiments (including randomized trials) do not provide anything approaching proof and in fact may be controversial, contradictory, or nonreproducible. If randomized clinical trials provided proof, we would never need to do more than one of them on a given hypothesis. Neither physical nor experimental science is immune to such problems, as demonstrated by episodes such as the experimental "discovery" (later refuted) of cold fusion (Taubes, 1993).

Some experimental scientists hold that epidemiologic relations are only suggestive and believe that detailed laboratory study of mechanisms within single individuals can reveal cause—effect relations with certainty. This view overlooks the fact that *all* relations are suggestive in exactly the manner discussed by Hume. Even the most careful and detailed mechanistic dissection of individual events cannot provide more than associations, albeit at a finer level. Laboratory studies often involve a degree of observer control that cannot be approached in epidemiology; it is only this control, not the level of observation, that can strengthen the inferences from laboratory studies. And again, such control is no guarantee against error. In addition, neither scientists nor decision makers are often highly persuaded when only mechanistic evidence from the laboratory is available.

All of the fruits of scientific work, in epidemiology or other disciplines, are at best only tentative formulations of a description of nature, even when the work itself is carried out without mistakes. The tentativeness of our knowledge does not prevent practical applications, but it should keep us skeptical and critical, not only of everyone else's work, but of our own as well. Sometimes etiologic hypotheses enjoy an extremely high, universally or almost universally shared, degree of certainty. The hypothesis that cigarette smoking causes lung cancer is one of the best-known examples. These hypotheses rise above "tentative" acceptance and are the closest we can come to "proof." But even

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these hypotheses are not "proved" with the degree of absolute certainty that accompanies the proof of a mathematical theorem.

CAUSAL INFERENCE IN EPIDEMIOLOGY

Etiologic knowledge about epidemiologic hypotheses is often scant, making the hypotheses themselves at times little more than vague statements of causal association between exposure and disease, such as "smoking causes cardiovascular disease." These vague hypotheses have only vague consequences that can be difficult to test. To cope with this vagueness, epidemiologists usually focus on testing the negation of the causal hypothesis, that is, the null hypothesis that the exposure does not have a causal relation to disease. Then, any observed association can potentially refute the hypothesis, subject to the assumption (auxiliary hypothesis) that biases and chance fluctuations are not solely responsible for the observation.

TESTS OF COMPETING EPIDEMIOLOGIC THEORIES

If the causal mechanism is stated specifically enough, epidemiologic observations can provide crucial tests of competing, non-null causal hypotheses. For example, when toxic-shock syndrome was first studied, there were two competing hypotheses about the causal agent. Under one hypothesis, it was a chemical in the tampon, so that women using tampons were exposed to the agent directly from the tampon. Under the other hypothesis, the tampon acted as a culture medium for staphylococci that produced a toxin. Both hypotheses explained the relation of toxic-shock occurrence to tampon use. The two hypotheses, however, led to opposite predictions about the relation between the frequency of changing tampons and the rate of toxic shock. Under the hypothesis of a chemical agent, more frequent changing of the tampon would lead to more exposure to the agent and possible absorption of a greater overall dose. This hypothesis predicted that women who changed tampons more frequently would have a higher rate than women who changed tampons infrequently. The culture-medium hypothesis predicts that women who change tampons frequently would have a lower rate than those who change tampons less frequently, because a short duration of use for each tampon would prevent the staphylococci from multiplying enough to produce a damaging dose of toxin. Thus, epidemiologic research, by showing that infrequent changing of tampons was associated with a higher rate of toxic shock, refuted the chemical theory in the form presented. There was, however, a third hypothesis that a chemical in some tampons (e.g., oxygen content) improved their performance as culture media. This chemical-promotor hypothesis made the same prediction about the association with frequency of changing tampons as the microbial toxin hypothesis (Lanes and Rothman, 1990).

Another example of a theory that can be easily tested by epidemiologic data relates to the observation that women who took replacement estrogen therapy had a considerably elevated rate of endometrial cancer. Horwitz and Feinstein (1978) conjectured a competing theory to explain the association: They proposed that women taking estrogen experienced symptoms such as bleeding that induced them to consult a physician. The resulting diagnostic workup led to the detection of endometrial cancer at an earlier stage in these women, as compared with women who were not taking estrogens. Horwitz and Feinstein argued that the association arose from this detection bias, claiming that without the bleeding-induced workup, many of these cancers would not have been detected at all. Many epidemiologic observations were used to evaluate these competing hypotheses. The detection-bias theory predicted that women who had used estrogens for only a short time would have the greatest elevation in their rate, as the symptoms related to estrogen use that led to the medical consultation tended to appear soon after use began. Because the association of recent estrogen use and endometrial cancer was the same in both long- and short-term estrogen users, the detection-bias theory was refuted as an explanation for all but a small fraction of endometrial cancer cases occurring after estrogen use. Refutation of the detection-bias theory also depended on many other observations. Especially important was the theory's implication that there must be a huge reservoir of undetected endometrial cancer in the typical population of women to account for the much greater rate observed in estrogen users, an implication that was not borne out by further observations (Hutchison and Rothman, 1978).

The endometrial cancer example illustrates a critical point in understanding the process of causal inference in epidemiologic studies: Many of the hypotheses being evaluated in the interpretation of epidemiologic studies are auxiliary hypotheses in the sense that they are independent of the presence, absence, or direction of any causal connection between the study exposure and the disease. For example, explanations of how specific types of bias could have distorted an association between exposure and disease are the usual alternatives to the primary study hypothesis. Much of the interpretation of epidemiologic studies amounts to the testing of such auxiliary explanations for

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observed associations.

In practice, how do epidemiologists separate causal from noncausal explanations? Despite philosophic criticisms of inductive inference, inductively oriented considerations are often used as criteria for making such inferences (Weed and Gorelic, 1996). If a set of necessary and sufficient causal criteria could be used to distinguish causal from noncausal relations in epidemiologic studies, the job of the scientist would be eased considerably. With such criteria, all the concerns about the logic or lack thereof in causal inference could be subsumed: It would only be necessary to consult the checklist of criteria to see if a relation were causal. We know from the philosophy reviewed earlier that a set of sufficient criteria does not exist. Nevertheless, lists of causal criteria have become popular, possibly because they seem to provide a road map through complicated territory, and perhaps because they suggest hypotheses to be evaluated in a given problem.

A commonly used set of criteria was based on a list of considerations or "viewpoints" proposed by Sir Austin Bradford Hill (1965). Hill's list was an expansion of a list offered previously in the landmark U.S. Surgeon General's report *Smoking and Health* (1964), which in turn was anticipated by the inductive canons of John Stuart Mill (1862) and the rules given by Hume (1739). Subsequently, others, especially Susser, have further developed causal considerations (Kaufman and Poole, 2000).

Hill suggested that the following considerations in attempting to distinguish causal from non-causal associations that were already "perfectly clear-cut and beyond what we would care to attribute to the play of chance": (1) strength, (2) consistency, (3) specificity, (4) temporality, (5) biologic gradient, (6) plausibility, (7) coherence, (8) experimental evidence, and (9) analogy. Hill emphasized that causal inferences cannot be based on a set of rules, condemned emphasis on statistical significance testing, and recognized the importance of many other factors in decision making (Phillips and Goodman, 2004). Nonetheless, the misguided but popular view that his considerations should be used as criteria for causal inference makes it necessary to examine them in detail.

Strength

Hill argued that strong associations are particularly compelling because, for weaker associations, it is "easier" to imagine what today we would call an unmeasured confounder that might be responsible for the association. Several years earlier, Cornfield et al. (1959) drew similar conclusions. They concentrated on a single hypothetical confounder that, by itself, would explain entirely an observed association. They expressed a strong preference for ratio measures of strength, as opposed to difference measures, and focused on how the observed estimate of a risk ratio provides a minimum for the association that a completely explanatory confounder must have with the exposure (rather than a minimum for the confounder—disease association). Of special importance, Cornfield et al. acknowledged that having only a weak association does not rule out a causal connection (Rothman and Poole, 1988). Today, some associations, such as those between smoking and cardiovascular disease or between environmental tobacco smoke and lung cancer, are accepted by most as causal even though the associations are considered weak.

Counterexamples of strong but noncausal associations are also not hard to find; any study with strong confounding illustrates the phenomenon. For example, consider the strong relation between Down syndrome and birth rank, which is confounded by the relation between Down syndrome and maternal age. Of course, once the confounding factor is identified, the association is diminished by controlling for the factor.

These examples remind us that a strong association is neither necessary nor sufficient for causality, and that weakness is neither necessary nor sufficient for absence of causality. A strong association

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bears only on hypotheses that the association is entirely or partially due to unmeasured confounders or other source of modest bias.

Consistency

To most observers, consistency refers to the repeated observation of an association in different populations under different circumstances. Lack of consistency, however, does not rule out a causal association, because some effects are produced by their causes only under unusual circumstances. More precisely, the effect of a causal agent cannot occur unless the complementary component causes act or have already acted to complete a sufficient cause. These conditions will not always be met. Thus, transfusions can cause infection with the human immunodeficiency virus, but they do not always do so: The virus must also be present. Tampon use can cause toxic-shock syndrome, but only rarely, when certain other, perhaps unknown, conditions are met. Consistency is apparent only after all the relevant details of a causal mechanism are understood, which is to say very seldom. Furthermore, even studies of exactly the same phenomena can be expected to yield different results simply because they differ in their methods and random errors. Consistency serves only to rule out hypotheses that the association is attributable to some factor that varies across studies.

One mistake in implementing the consistency criterion is so common that it deserves special mention. It is sometimes claimed that a literature or set of results is inconsistent simply because some results are "statistically significant" and some are not. This sort of evaluation is completely fallacious even if one accepts the use of significance testing methods. The results (effect estimates) from a set of studies could all be identical even if many were significant and many were not, the difference in significance arising solely because of differences in the standard errors or sizes of the studies. Conversely, the results could be significantly in conflict even if all were all were nonsignificant individually, simply because in aggregate an effect could be apparent in some subgroups but not others (see Chapter 33). The fallacy of judging consistency by comparing *P*-values or statistical significance is not eliminated by "standardizing" estimates (i.e., dividing them by the standard deviation of the outcome, multiplying them by the standard deviation of the exposure, or both); in fact it is worsened, as such standardization can create differences where none exists, or mask true differences (Greenland et al., 1986, 1991; see Chapters 21 and 33).

Specificity

The criterion of specificity has two variants. One is that a cause leads to a single effect, not multiple effects. The other is that an effect has one cause, not multiple causes. Hill mentioned both of them. The former criterion, specificity of effects, was used as an argument in favor of a causal interpretation of the association between smoking and lung cancer and, in an act of circular reasoning, in favor of ratio comparisons and not differences as the appropriate measures of strength. When ratio measures were examined, the association of smoking to diseases looked "quantitatively specific" to lung cancer. When difference measures were examined, the association appeared to be nonspecific, with several diseases (other cancers, coronary heart disease, etc.) being at least as strongly associated with smoking as lung cancer was. Today we know that smoking affects the risk of many diseases and that the difference comparisons were accurately portraying this lack of specificity. Unfortunately, however, the historical episode of the debate over smoking and health is often cited today as justification for the specificity criterion and for using ratio comparisons to measure strength of association. The proper lessons to learn from that episode should be just the opposite.

Weiss (2002) argued that specificity can be used to distinguish some causal hypotheses from noncausal hypotheses, when the causal hypothesis predicts a relation with one outcome but no relation with another outcome. His argument is persuasive when, in addition to the causal hypothesis, one has an alternative noncausal hypothesis that predicts a nonspecific association. Weiss offered the example of screening sigmoidoscopy, which was associated in case-control studies with a 50% to 70% reduction in mortality from distal tumors of the rectum and tumors of the distal colon, within the reach of the sigmoidoscope, but no reduction in mortality from tumors elsewhere in the colon. If the effect of screening sigmoidoscopy were not specific to the distal colon tumors, it would lend support not to all noncausal theories to explain the association, as Weiss suggested, but only to those noncausal theories that would have predicted a nonspecific association. Thus, specificity can

come into play when it can be logically deduced from the causal hypothesis in question and when nonspecificity can be logically deduced from one or more noncausal hypotheses.

Temporality

Temporality refers to the necessity that the cause precede the effect in time. This criterion is inarguable, insofar as any claimed observation of causation must involve the putative cause C preceding the putative effect D. It does *not*, however, follow that a reverse time order is evidence against the hypothesis that C can cause D. Rather, observations in which C followed D merely show that C could not have caused D in these instances; they provide no evidence for or against the hypothesis that C can cause D in those instances in which it precedes D. Only if it is found that C cannot precede D can we dispense with the causal hypothesis that C *could* cause D.

Biologic Gradient

Biologic gradient refers to the presence of a dose–response or exposure–response curve with an expected shape. Although Hill referred to a "linear" gradient, without specifying the scale, a linear gradient on one scale, such as the risk, can be distinctly nonlinear on another scale, such as the log risk, the odds, or the log odds. We might relax the expectation from linear to strictly monotonic (steadily increasing or decreasing) or even further merely to monotonic (a gradient that never changes direction). For example, more smoking means more carcinogen exposure and more tissue damage, hence more opportunity for carcinogenesis. Some causal associations, however, show a rapid increase in response (an approximate threshold effect) rather than a strictly monotonic trend. An example is the association between DES and adenocarcinoma of the vagina. A possible explanation is that the doses of DES that were administered were all sufficiently great to produce the maximum effect from DES. Under this hypothesis, for all those exposed to DES, the development of disease would depend entirely on other component causes.

The somewhat controversial topic of alcohol consumption and mortality is another example. Death rates are higher among nondrinkers than among moderate drinkers, but they ascend to the highest levels for heavy drinkers. There is considerable debate about which parts of the J-shaped dose–response curve are causally related to alcohol consumption and which parts are noncausal artifacts stemming from confounding or other biases. Some studies appear to find only an increasing relation between alcohol consumption and mortality, possibly because the categories of alcohol consumption are too broad to distinguish different rates among moderate drinkers and nondrinkers, or possibly because they have less confounding at the lower end of the consumption scale.

Associations that do show a monotonic trend in disease frequency with increasing levels of exposure are not necessarily causal. Confounding can result in a monotonic relation between a noncausal risk factor and disease if the confounding factor itself demonstrates a biologic gradient in its relation with disease. The relation between birth rank and Down syndrome mentioned earlier shows a strong biologic gradient that merely reflects the progressive relation between maternal age and occurrence of Down syndrome.

These issues imply that the existence of a monotonic association is neither necessary nor sufficient for a causal relation. A nonmonotonic relation only refutes those causal hypotheses specific enough to predict a monotonic dose–response curve.

Plausibility

Plausibility refers to the scientific plausibility of an association. More than any other criterion, this one shows how narrowly systems of causal criteria are focused on epidemiology. The starting point is an epidemiologic association. In asking whether it is causal or not, one of the considerations we take into account is its plausibility. From a less parochial perspective, the entire enterprise of causal inference would be viewed as the act of determining how plausible a causal *hypothesis* is. One of the considerations we would take into account would be epidemiologic associations, if they are available. Often they are not, but causal inference must be done nevertheless, with inputs from toxicology, pharmacology, basic biology, and other sciences.

Just as epidemiology is not essential for causal inference, plausibility can change with the times. Sartwell (1960) emphasized this point, citing remarks of Cheever in 1861, who had been commenting on the etiology of typhus before its mode of transmission (via body lice) was known:

Chapter 2 • Causation and Causal Inference

It could be no more ridiculous for the stranger who passed the night in the steerage of an emigrant ship to ascribe the typhus, which he there contracted, to the vermin with which bodies of the sick might be infested. An adequate cause, one reasonable in itself, must correct the coincidences of simple experience.

What was to Cheever an implausible explanation turned out to be the correct explanation, because it was indeed the vermin that caused the typhus infection. Such is the problem with plausibility: It is too often based not on logic or data, but only on prior beliefs. This is not to say that biologic knowledge should be discounted when a new hypothesis is being evaluated, but only to point out the difficulty in applying that knowledge.

The Bayesian approach to inference attempts to deal with this problem by requiring that one quantify, on a probability (0 to 1) scale, the certainty that one has in prior beliefs, as well as in new hypotheses. This quantification displays the dogmatism or open-mindedness of the analyst in a public fashion, with certainty values near 1 or 0 betraying a strong commitment of the analyst for or against a hypothesis. It can also provide a means of testing those quantified beliefs against new evidence (Howson and Urbach, 1993). Nevertheless, no approach can transform plausibility into an objective causal criterion.

Coherence

Taken from the U.S. Surgeon General's Smoking and Health (1964), the term coherence implies that a cause-and-effect interpretation for an association does not conflict with what is known of the natural history and biology of the disease. The examples Hill gave for coherence, such as the histopathologic effect of smoking on bronchial epithelium (in reference to the association between smoking and lung cancer) or the difference in lung cancer incidence by sex, could reasonably be considered examples of plausibility, as well as coherence; the distinction appears to be a fine one. Hill emphasized that the absence of coherent information, as distinguished, apparently, from the presence of conflicting information, should not be taken as evidence against an association being considered causal. On the other hand, the presence of conflicting information may indeed refute a hypothesis, but one must always remember that the conflicting information may be mistaken or misinterpreted. An example mentioned earlier is the "inhalation anomaly" in smoking and lung cancer, the fact that the excess of lung cancers seen among smokers seemed to be concentrated at sites in the upper airways of the lung. Several observers interpreted this anomaly as evidence that cigarettes were not responsible for the excess. Other observations, however, suggested that cigarette-borne carcinogens were deposited preferentially where the excess was observed, and so the anomaly was in fact consistent with a causal role for cigarettes (Wald, 1985).

Experimental Evidence

To different observers, experimental evidence can refer to clinical trials, to laboratory experiments with rodents or other nonhuman organisms, or to both. Evidence from human experiments, however, is seldom available for epidemiologic research questions, and animal evidence relates to different species and usually to levels of exposure very different from those that humans experience. Uncertainty in extrapolations from animals to humans often dominates the uncertainty of quantitative risk assessments (Freedman and Zeisel, 1988; Crouch et al., 1997).

To Hill, however, experimental evidence meant something else: the "experimental, or semi-experimental evidence" obtained from reducing or eliminating a putatively harmful exposure and seeing if the frequency of disease subsequently declines. He called this the strongest possible evidence of causality that can be obtained. It can be faulty, however, as the "semi-experimental" approach is nothing more than a "before-and-after" time trend analysis, which can be confounded or otherwise biased by a host of concomitant secular changes. Moreover, even if the removal of exposure does causally reduce the frequency of disease, it might not be for the etiologic reason hypothesized. The draining of a swamp near a city, for instance, would predictably and causally reduce the rate of yellow fever or malaria in that city the following summer. But it would be a mistake to call this observation the strongest possible evidence of a causal role of miasmas (Poole, 1999).

Section I • Basic Concepts

Analogy

Whatever insight might be derived from analogy is handicapped by the inventive imagination of scientists who can find analogies everywhere. At best, analogy provides a source of more elaborate hypotheses about the associations under study; absence of such analogies reflects only lack of imagination or experience, not falsity of the hypothesis.

We might find naive Hill's examples in which reasoning by analogy from the thalidomide and rubella tragedies made it more likely to him that other medicines and infections might cause other birth defects. But such reasoning is common; we suspect most people find it more credible that smoking might cause, say, stomach cancer, because of its associations, some widely accepted as causal, with cancers in other internal and gastrointestinal organs. Here we see how the analogy criterion can be at odds with either of the two specificity criteria. The more apt the analogy, the less specific are the effects of a cause or the less specific the causes of an effect.

Summary

As is evident, the standards of epidemiologic evidence offered by Hill are saddled with reservations and exceptions. Hill himself was ambivalent about their utility. He did not use the word *criteria* in the speech. He called them "viewpoints" or "perspectives." On the one hand, he asked, "In what circumstances can we pass from this observed *association* to a verdict of *causation*?" (emphasis in original). Yet, despite speaking of verdicts on causation, he disagreed that any "hard-and-fast rules of evidence" existed by which to judge causation: "None of my nine viewpoints can bring indisputable evidence for or against the cause-and-effect hypothesis and none can be required as a sine qua non" (Hill, 1965).

Actually, as noted above, the fourth viewpoint, temporality, is *a sine qua non* for causal explanations of observed associations. Nonetheless, it does not bear on the hypothesis that an exposure is capable of causing a disease in situations as yet unobserved (whether in the past or the future). For suppose every exposed case of disease ever reported had received the exposure after developing the disease. This reversed temporal relation would imply that exposure had not caused disease among these reported cases, and thus would refute the hypothesis that it had. Nonetheless, it would *not* refute the hypothesis that the exposure is *capable* of causing the disease, or that it had caused the disease in unobserved cases. It would mean only that we have no worthwhile epidemiologic evidence relevant to that hypothesis, for we had not yet seen what became of those exposed before disease occurred relative to those unexposed. Furthermore, what appears to be a causal sequence could represent reverse causation if preclinical symptoms of the disease lead to exposure, and then overt disease follows, as when patients in pain take analgesics, which may be the result of disease that is later diagnosed, rather than a cause.

Other than temporality, there is no necessary or sufficient criterion for determining whether an observed association is causal. Only when a causal hypothesis is elaborated to the extent that one can predict from it a particular form of consistency, specificity, biologic gradient, and so forth, can "causal criteria" come into play in evaluating causal hypotheses, and even then they do not come into play in evaluating the general hypothesis per se, but only some specific causal hypotheses, leaving others untested.

This conclusion accords with the views of Hume and many others that causal inferences cannot attain the certainty of logical deductions. Although some scientists continue to develop causal considerations as aids to inference (Susser, 1991), others argue that it is detrimental to cloud the inferential process by considering checklist criteria (Lanes and Poole, 1984). An intermediate, refutationist approach seeks to transform proposed criteria into deductive tests of causal hypotheses (Maclure, 1985; Weed, 1986). Such an approach helps avoid the temptation to use causal criteria simply to buttress pet theories at hand, and instead allows epidemiologists to focus on evaluating competing causal theories using crucial observations. Although this refutationist approach to causal inference may seem at odds with the common implementation of Hill's viewpoints, it actually seeks to answer the fundamental question posed by Hill, and the ultimate purpose of the viewpoints he promulgated:

What [the nine viewpoints] can do, with greater or less strength, is to help us to make up our minds on the fundamental question—is there any other way of explaining the set of facts before us, is there any other answer equally, or more, likely than cause and effect? (Hill, 1965)

Chapter 2 • Causation and Causal Inference

The crucial phrase "equally or more likely than cause and effect" suggests to us a subjective assessment of the certainty, or probability of the causal hypothesis at issue relative to another hypothesis. Although Hill wrote at a time when expressing uncertainty as a probability was unpopular in statistics, it appears from his statement that, for him, causal inference is a subjective matter of degree of personal belief, certainty, or conviction. In any event, this view is precisely that of subjective Bayesian statistics (Chapter 18).

It is unsurprising that case studies (e.g., Weed and Gorelick, 1996) and surveys of epidemiologists (Holman et al., 2001) show, contrary to the rhetoric that often attends invocations of causal criteria, that epidemiologists have *not* agreed on a set of causal criteria or on how to apply them. In one study in which epidemiologists were asked to employ causal criteria to fictional summaries of epidemiologic literatures, the agreement was only slightly greater than would have been expected by chance (Holman et al., 2001). The typical use of causal criteria is to make a case for a position for or against causality that has been arrived at by other, unstated means. Authors pick and choose among the criteria they deploy, and define and weight them in *ad hoc* ways that depend only on the exigencies of the discussion at hand. In this sense, causal criteria appear to function less like standards or principles and more like values (Poole, 2001b), which vary across individual scientists and even vary within the work of a single scientist, depending on the context and time. Thus universal and objective causal criteria, if they exist, have yet to be identified.

CHAPTER 8

Case-Control Studies

Kenneth J. Rothman, Sander Greenland, and Timothy L. Lash

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The use and understanding of case-control studies is one of the most important methodologic developments of modern epidemiology. Conceptually, there are clear links from randomized experiments to nonrandomized cohort studies, and from nonrandomized cohort studies to case-control studies. Case-control studies nevertheless differ enough from the scientific paradigm of experimentation that a casual approach to their conduct and interpretation invites misconception. In this chapter we review case-control study designs and contrast their advantages and disadvantages with cohort designs. We also consider variants of the basic case-control study design.

Conventional wisdom about case-control studies is that they do not yield estimates of effect that are as valid as measures obtained from cohort studies. This thinking may reflect common misunderstandings in conceptualizing case-control studies, which will be clarified later. It may also reflect concern about biased exposure information and selection in case-control studies. For example, if exposure information comes from interviews, cases will usually have reported the exposure information after learning of their diagnosis. Diagnosis may affect reporting in a number of ways, for example, by improving memory, thus enhancing sensitivity among cases, or by provoking more false memory of exposure, thus reducing specificity among cases. Furthermore, the disease may itself cloud memory and thus reduce sensitivity. These phenomena are examples of *recall bias*. Disease cannot affect exposure information collected before the disease occurred, however. Thus exposure information taken from records created before the disease occurs will not be subject to recall bias, regardless of whether the study is a cohort or a case-control design.

Conversely, cohort studies are not immune from problems often thought to be particular to case-control studies. For example, while a cohort study may gather information on exposure for an entire source population at the outset of the study, it still requires tracing of subjects to ascertain

exposure variation and outcomes. If the success of this tracing is related to the exposure and the outcome, the resulting selection bias will behave analogously to that often raised as a concern in case-control studies (Greenland, 1977; Chapter 12). Similarly, cohort studies sometimes use recall to reconstruct or impute exposure history (retrospective evaluation) and are vulnerable to recall bias if this reconstruction is done after disease occurrence. Thus, although more opportunity for recall and selection bias may arise in typical case-control studies than in typical prospective cohort studies, each study must be considered in detail to evaluate its vulnerability to bias, regardless of its design.

Conventional wisdom also holds that cohort studies are useful for evaluating the range of effects related to a single exposure, whereas case-control studies provide information only about the one disease that afflicts the cases. This thinking conflicts with the idea that case-control studies can be viewed simply as more efficient cohort studies. Just as one can choose to measure more than one disease outcome in a cohort study, it is possible to conduct a set of case-control studies nested within the same population using several disease outcomes as the case series. The case-cohort study (see below) is particularly well suited to this task, allowing one control group to be compared with several series of cases. Whether or not the case-cohort design is the form of case-control study that is used, case-control studies do not have to be characterized as being limited with respect to the number of disease outcomes that can be studied.

For diseases that are sufficiently rare, cohort studies become impractical and case-control studies become the only useful alternative. On the other hand, if exposure is rare, ordinary case-control studies are inefficient, and one must use methods that selectively recruit additional exposed subjects, such as special cohort studies or two-stage designs. If both the exposure and the outcome are rare, two-stage designs may be the only informative option, as they employ oversampling of both exposed and diseased subjects.

As understanding of the principles of case-control studies has progressed, the reputation of case-control studies has also improved. Formerly, it was common to hear case-control studies referred to disparagingly as "retrospective" studies, a term that should apply to only some case-control studies and applies as well to some cohort studies (see Chapter 6). Although case-control studies do present more opportunities for bias and mistaken inference than cohort studies, these opportunities come as a result of the relative ease with which a case-control study can be mounted. Because it need not be extremely expensive or time-consuming to conduct a case-control study, many studies have been conducted by naive investigators who do not understand or implement the basic principles of valid case-control design. Occasionally, such haphazard research can produce valuable results, but often the results are wrong because basic principles have been violated. The bad reputation once suffered by case-control studies stems more from instances of poor conduct and overinterpretation of results than from any inherent weakness in the approach.

Ideally, a case-control study can be conceptualized as a more efficient version of a corresponding cohort study. Under this conceptualization, the cases in the case-control study are the same cases as would ordinarily be included in the cohort study. Rather than including all of the experience of the source population that gave rise to the cases (the study base), as would be the usual practice in a cohort design, controls are selected from the source population. Wacholder (1996) describes this paradigm of the case-control study as a cohort study with data missing at random and by design. The sampling of controls from the population that gave rise to the cases affords the efficiency gain of a case-control design over a cohort design. The controls provide an estimate of the prevalence of the exposure and covariates in the source population. When controls are selected from members of the population who were at risk for disease at the beginning of the study's follow-up period, the case-control odds ratio estimates the risk ratio that would be obtained from a cohort design. When controls are selected from members of the population who were noncases at the times that each case occurs, or otherwise in proportion to the person-time accumulated by the cohort, the case-control odds ratio estimates the rate ratio that would be obtained from a cohort design. Finally, when controls are selected from members of the population who were noncases at the end of the study's follow-up period, the case-control odds ratio estimates the incidence odds ratio that would be obtained from a cohort design. With each control-selection strategy, the odds-ratio calculation is the same, but the measure of effect estimated by the odds ratio differs. Study designs that implement each of these control selection paradigms will be discussed after topics that are common to all designs.

COMMON ELEMENTS OF CASE-CONTROL STUDIES

In a cohort study, the numerator and denominator of each disease frequency (incidence proportion, incidence rate, or incidence odds) are measured, which requires enumerating the entire population and keeping it under surveillance—or using an existing registry—to identify cases over the follow-up period. A valid case-control study observes the population more efficiently by using a control series in place of complete assessment of the denominators of the disease frequencies. The cases in a case-control study should be the same people who would be considered cases in a cohort study of the same population.

PSEUDO-FREQUENCIES AND THE ODDS RATIO

The primary goal for control selection is that the exposure distribution among controls be the same as it is in the source population of cases. The rationale for this goal is that, if it is met, we can use the control series in place of the denominator information in measures of disease frequency to determine the ratio of the disease frequency in exposed people relative to that among unexposed people. This goal will be met if we can sample controls from the source population such that the ratio of the number of exposed controls (B_1) to the total exposed experience of the source population is the same as the ratio of the number of unexposed controls (B_0) to the unexposed experience of the source population, apart from sampling error. For most purposes, this goal need only be followed within strata of factors that will be used for stratification in the analysis, such as factors used for restriction or matching (Chapters 11, 15, 16, and 21).

Using person-time to illustrate, the goal requires that B_1 has the same ratio to the amount of exposed person-time (T_1) as B_0 has to the amount of unexposed person-time (T_0) , apart from sampling error:

$$\frac{B_1}{T_1} = \frac{B_0}{T_0}$$

Here B_1/T_1 and B_0/T_0 are the control sampling rates—that is, the number of controls selected per unit of person-time. Suppose that A_1 exposed cases and A_0 unexposed cases occur over the study period. The exposed and unexposed rates are then

$$I_1 = \frac{A_1}{T_1} \quad \text{and} \quad I_0 = \frac{A_0}{T_0}$$

We can use the frequencies of exposed and unexposed controls as substitutes for the actual denominators of the rates to obtain exposure-specific case-control ratios, or *pseudo-rates*:

$$Pseudo-rate_1 = \frac{A_1}{B_1}$$

and

$$Pseudo-rate_0 = \frac{A_0}{B_0}$$

These pseudo-rates have no epidemiologic interpretation by themselves. Suppose, however, that the control sampling rates B_1/T_1 and B_0/T_0 are equal to the same value r, as would be expected if controls are selected independently of exposure. If this common sampling rate r is known, the actual incidence rates can be calculated by simple algebra because, apart from sampling error, B_1/r should equal the amount of exposed person-time in the source population and B_0/r should equal the amount of unexposed person-time in the source population: $B_1/r = B_1/(B_1/T_1) = T_1$ and $B_0/r = B_0/(B_0/T_0) = T_0$. To get the incidence rates, we need only multiply each pseudo-rate by the common sampling rate, r.

If the common sampling rate is not known, which is often the case, we can still compare the sizes of the pseudo-rates by division. Specifically, if we divide the pseudo-rate for exposed by the pseudo-rate for unexposed, we obtain

$$\frac{\text{Pseudo-rate}_1}{\text{Pseudo-rate}_0} = \frac{A_1/B_1}{A_0/B_0} = \frac{A_1/[(B_1/T_1)T_1]}{A_0/[(B_0/T_0)T_0]} = \frac{A_1/(r \cdot T_1)}{A_0/(r \cdot T_0)} = \frac{A_1/T_1}{A_0/T_0}$$

Section II • Study Design and Conduct

In other words, the ratio of the pseudo-rates for the exposed and unexposed is an estimate of the ratio of the incidence rates in the source population, provided that the control sampling rate is independent of exposure. Thus, using the case-control study design, one can estimate the incidence rate ratio in a population without obtaining information on every subject in the population. Similar derivations in the following section on variants of case-control designs show that one can estimate the risk ratio by sampling controls from those at risk for disease at the beginning of the follow-up period (case-cohort design) and that one can estimate the incidence odds ratio by sampling controls from the noncases at the end of the follow-up period (cumulative case-control design). With these designs, the pseudo-frequencies correspond to the incidence proportions and incidence odds, respectively, multiplied by common sampling rates.

There is a statistical penalty for using a sample of the denominators rather than measuring the person-time experience for the entire source population: The precision of the estimates of the incidence rate ratio from a case-control study is less than the precision from a cohort study of the entire population that gave rise to the cases (the source population). Nevertheless, the loss of precision that stems from sampling controls will be small if the number of controls selected per case is large (usually four or more). Furthermore, the loss is balanced by the cost savings of not having to obtain information on everyone in the source population. The cost savings might allow the epidemiologist to enlarge the source population and so obtain more cases, resulting in a better overall estimate of the incidence-rate ratio, statistically and otherwise, than would be possible using the same expenditures to conduct a cohort study.

The ratio of the two pseudo-rates in a case-control study is usually written as A_1B_0/A_0B_1 and is sometimes called the *cross-product ratio*. The cross-product ratio in a case-control study can be viewed as the ratio of cases to controls among the exposed subjects (A_1/B_1) , divided by the ratio of cases to controls among the unexposed subjects (A_0/B_0) . This ratio can also be viewed as the odds of being exposed among cases (A_1/A_0) divided by the odds of being exposed among controls (B_1/B_0) , in which case it is termed the *exposure odds ratio*. While either interpretation will give the same result, viewing this odds ratio as the ratio of case-control ratios shows more directly how the control group substitutes for the denominator information in a cohort study and how the ratio of pseudo-frequencies gives the same result as the ratio of the incidence rates, incidence proportion, or incidence odds in the source population, if sampling is independent of exposure.

One point that we wish to emphasize is that *nowhere* in the preceding discussion did we have to assume that the disease under study is "rare." In general, the rare-disease assumption is *not* needed in case-control studies. Just as for cohort studies, however, neither the incidence odds ratio nor the rate ratio should be expected to be a good approximation to the risk ratio or to be collapsible across strata of a risk factor (even if the factor is not a confounder) unless the incidence proportion is less than about 0.1 for every combination of the exposure and the factor (Chapter 4).

DEFINING THE SOURCE POPULATION

If the cases are a representative sample of all cases in a precisely defined and identified population and the controls are sampled directly from this source population, the study is said to be *population-based* or a *primary* base study. For a population-based case-control study, random sampling of controls may be feasible if a population registry exists or can be compiled. When random sampling from the source population of cases is feasible, it is usually the most desirable option.

Random sampling of controls does not necessarily mean that every person should have an equal probability of being selected to be a control. As explained earlier, if the aim is to estimate the incidence-rate ratio, then we would employ longitudinal (density) sampling, in which a person's control selection probability is proportional to the person's time at risk. For example, in a case-control study nested within an occupational cohort, workers on an employee roster will have been followed for varying lengths of time, and a random sampling scheme should reflect this varying time to estimate the incidence-rate ratio.

When it is not possible to identify the source population explicitly, simple random sampling is not feasible and other methods of control selection must be used. Such studies are sometimes called studies of *secondary* bases, because the source population is identified secondarily to the definition of a case-finding mechanism. A secondary source population or "secondary base" is therefore a source population that is defined from (secondary to) a given case series.

Consider a case-control study in which the cases are patients treated for severe psoriasis at the Mayo Clinic. These patients come to the Mayo Clinic from all corners of the world. What is the specific source population that gives rise to these cases? To answer this question, we would have to know exactly who would go to the Mayo Clinic if he or she had severe psoriasis. We cannot enumerate this source population, because many people in it do not know themselves that they would go to the Mayo Clinic for severe psoriasis, unless they actually developed severe psoriasis. This secondary source might be defined as a population spread around the world that constitutes those people who would go to the Mayo Clinic if they developed severe psoriasis. It is this secondary source from which the control series for the study would ideally be drawn. The challenge to the investigator is to apply eligibility criteria to the cases and controls so that there is good correspondence between the controls and this source population. For example, cases of severe psoriasis and controls might be restricted to those in counties within a certain distance of the Mayo Clinic, so that at least a geographic correspondence between the controls and the secondary source population could be assured. This restriction, however, might leave very few cases for study.

Unfortunately, the concept of a secondary base is often tenuously connected to underlying realities, and it can be highly ambiguous. For the psoriasis example, whether a person would go to the Mayo Clinic depends on many factors that vary over time, such as whether the person is encouraged to go by his regular physician and whether the person can afford to go. It is not clear, then, how or even whether one could precisely define, let alone sample from, the secondary base, and thus it is not clear that one could ensure that controls were members of the base at the time of sampling. We therefore prefer to conceptualize and conduct case-control studies as starting with a well-defined source population and then identify and recruit cases and controls to represent the disease and exposure experience of that population. When one instead takes a case series as a starting point, it is incumbent upon the investigator to demonstrate that a source population can be operationally defined to allow the study to be recast and evaluated relative to this source. Similar considerations apply when one takes a control series as a starting point, as is sometimes done (Greenland, 1985a).

CASE SELECTION

Ideally, case selection will amount to a direct sampling of cases within a source population. Therefore, apart from random sampling, all people in the source population who develop the disease of interest are presumed to be included as cases in the case-control study. It is not always necessary, however, to include all cases from the source population. Cases, like controls, can be randomly sampled for inclusion in the case-control study, so long as this sampling is independent of the exposure under study within strata of factors that will be used for stratification in the analysis. To see this, suppose we take only a fraction, f, of all cases. If this fraction is constant across exposure, and A_1 exposed cases and A_0 unexposed cases occur in the source population, then, apart from sampling error, the study odds ratio will be

$$\frac{A_1/B_1}{A_0/B_0} = \frac{fA_1/(r \cdot T_1)}{fA_0/(r \cdot T_0)} = \frac{A_1/T_1}{A_0/T_0}$$

as before. Of course, if fewer than all cases are sampled (f < 1), the study precision will be lower in proportion to f.

The cases identified in a single clinic or treated by a single medical practitioner are possible case series for case-control studies. The corresponding source population for the cases treated in a clinic is all people who would attend that clinic and be recorded with the diagnosis of interest if they had the disease in question. It is important to specify "if they had the disease in question" because clinics serve different populations for different diseases, depending on referral patterns and the reputation of the clinic in specific specialty areas. As noted above, without a precisely identified source population, it may be difficult or impossible to select controls in an unbiased fashion.

CONTROL SELECTION

The definition of the source population determines the population from which controls are sampled. Ideally, selection will involve direct sampling of controls from the source population. Based on the

principles explained earlier regarding the role of the control series, many general rules for control selection can be formulated. Two basic rules are that:

- 1. Controls should be selected from the same population—the source population—that gives rise to the study cases. If this rule cannot be followed, there needs to be solid evidence that the population supplying controls has an exposure distribution identical to that of the population that is the source of cases, which is a very stringent demand that is rarely demonstrable.
- 2. Within strata of factors that will be used for stratification in the analysis, controls should be selected independently of their exposure status, in that the sampling rate for controls (*r* in the previous discussion) should not vary with exposure.

If these rules and the corresponding case rules are met, then the ratio of pseudo-frequencies will, apart from sampling error, equal the ratio of the corresponding measure of disease frequency in the source population. If the sampling rate is known, then the actual measures of disease frequency can also be calculated. (If the sampling rates differ for exposed and unexposed cases or controls, but are known, the measures of disease frequency and their ratios can still be calculated using special correction formulas; see Chapters 15 and 19.) For a more detailed discussion of the principles of control selection in case-control studies, see Wacholder et al. (1992a, 1992b, 1992c).

When one wishes controls to represent person-time, sampling of the person-time should be constant across exposure levels. This requirement implies that the sampling *probability* of any person as a control should be proportional to the amount of person-time that person spends at risk of disease in the source population. For example, if in the source population one person contributes twice as much person-time during the study period as another person, the first person should have twice the probability of the second of being selected as a control. This difference in probability of selection is automatically induced by sampling controls at a steady rate per unit time over the period in which cases are sampled (*longitudinal* or *density* sampling), rather than by sampling all controls at a point in time (such as the start or end of the follow-up period). With longitudinal sampling of controls, a population member present for twice as long as another will have twice the chance of being selected.

If the objective of the study is to estimate a risk or rate ratio, it should be possible for a person to be selected as a control and yet remain eligible to become a case, so that person might appear in the study as both a control and a case. This possibility may sound paradoxical or wrong, but it is nevertheless correct. It corresponds to the fact that in a cohort study, a case contributes to both the numerator and the denominator of the estimated incidence.

Suppose the follow-up period spans 3 years, and a person free of disease in year 1 is selected as a potential control at year 1. This person should in principle remain eligible to become a case. Suppose this control now develops the disease at year 2 and now becomes a case in the study. How should such a person be treated in the analysis? Because the person did develop disease during the study period, many investigators would count the person as a case but not as a control. If the objective is to have the case-control odds ratio estimate the incidence odds ratio, then this decision would be appropriate. Recall, however, that if a follow-up study were being conducted, each person who develops disease would contribute not only to the numerator of the disease risk or rate but also to the persons or person-time tallied in the denominator. We want the control group to provide estimates of the relative size of the denominators of the incidence proportions or incidence rates for the compared groups. These denominators include all people who later become cases. Therefore, each case in a case-control study should be eligible to be a control before the time of disease onset, each control should be eligible to become a case as of the time of selection as a control, and a person selected as a control who later does develop the disease and is selected as a case should be included in the study both as a control and as a case (Sheehe, 1962; Miettinen, 1976a; Greenland and Thomas, 1982; Lubin and Gail, 1984; Robins et al., 1986a). If the controls are intended to represent person time and are selected longitudinally, similar arguments show that a person selected as a control should remain eligible to be selected as a control again, and thus might be included in the analysis repeatedly as a control (Lubin and Gail, 1984; Robins et al., 1986a).

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COMMON FALLACIES IN CONTROL SELECTION

In cohort studies, the study population is restricted to people at risk for the disease. Some authors have viewed case-control studies as if they were cohort studies done backwards, even going so far as to describe them as "trohoc" studies (Feinstein, 1973). Under this view, the argument was advanced that case-control studies ought to be restricted to those at risk for exposure (i.e., those with exposure opportunity). Excluding sterile women from a case-control study of an adverse effect of oral contraceptives and matching for duration of employment in an occupational study are examples of attempts to control for exposure opportunity. If the factor used for restriction (e.g., sterility) is unrelated to the disease, it will not be a confounder, and hence the restriction will yield no benefit to the validity of the estimate of effect. Furthermore, if the restriction reduces the study size, the precision of the estimate of effect will be reduced (Poole, 1986).

Another principle sometimes used in cohort studies is that the study cohort should be "clean" at start of follow-up, including only people who have never had the disease. Misapplying this principle to case-control design suggests that the control group ought to be "clean," including only people who are healthy, for example. Illness arising after the start of the follow-up period is not reason to exclude subjects from a cohort analysis, and such exclusion can lead to bias; similarly controls with illness that arose after exposure should not be removed from the control series. Nonetheless, in studies of the relation between cigarette smoking and colorectal cancer, certain authors recommended that the control group should exclude people with colon polyps, because colon polyps are associated with smoking and are precursors of colorectal cancer (Terry and Neugut, 1998). Such an exclusion actually reduces the prevalence of the exposure in the controls below that in the source population of cases and hence biases the effect estimates upward (Poole, 1999).

SOURCES FOR CONTROL SERIES

The following methods for control sampling apply when the source population cannot be explicitly enumerated, so random selection is not possible. All of these methods should only be implemented subject to the reservations about secondary bases described earlier.

Neighborhood Controls

If the source population cannot be enumerated, it may be possible to select controls through sampling of residences. This method is not straightforward. Usually, a geographic roster of residences is not available, so a scheme must be devised to sample residences without enumerating them all. For convenience, investigators may sample controls who are individually matched to cases from the same neighborhood. That is, after a case is identified, one or more controls residing in the same neighborhood as that case are identified and recruited into the study. If neighborhood is related to exposure, the matching should be taken into account in the analysis (see Chapter 16).

Neighborhood controls are often used when the cases are recruited from a convenient source, such as a clinic or hospital. Such usage can introduce bias, however, for the neighbors selected as controls may not be in the source population of the cases. For example, if the cases are from a particular hospital, neighborhood controls may include people who would not have been treated at the same hospital had they developed the disease. If being treated at the hospital from which cases are identified is related to the exposure under study, then using neighborhood controls would introduce a bias. As an extreme example, suppose the hospital in question were a U.S. Veterans Administration hospital. Patients at these hospitals tend to differ from their neighbors in many ways. One obvious way is in regard to service history. Most patients at Veterans Administration hospitals have served in the U.S. military, whereas only a minority of their neighbors will have done so. This difference in life history can lead to differences in exposure histories (e.g., exposures associated with combat or weapons handling). For any given study, the suitability of using neighborhood controls needs to be evaluated with regard to the study variables on which the research focuses.

Random-Digit Dialing

Sampling of households based on random selection of telephone numbers is intended to simulate sampling randomly from the source population. *Random-digit dialing*, as this method has been called (Waksberg, 1978), offers the advantage of approaching all households in a designated area,

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even those with unlisted telephone numbers, through a simple telephone call. The method requires considerable attention to details, however, and carries no guarantee of unbiased selection.

First, case eligibility should include residence in a house that has a telephone, so that cases and controls come from the same source population. Second, even if the investigator can implement a sampling method so that every telephone has the same probability of being called, there will not necessarily be the same probability of contacting each eligible control subject, because households vary in the number of people who reside in them, the amount of time someone is at home, and the number of operating phones. Third, making contact with a household may require many calls at various times of day and various days of the week, demanding considerable labor; many dozens of telephone calls may be required to obtain a control subject meeting specific eligibility characteristics (Wacholder et al., 1992b). Fourth, some households use answering machines, voicemail, or caller identification to screen calls and may not answer or return unsolicited calls. Fifth, the substitution of mobile telephones for land lines by some households further undermines the assumption that population members can be selected randomly by random-digit dialing. Finally, it may be impossible to distinguish accurately business from residential telephone numbers, a distinction required to calculate the proportion of nonresponders.

Random-digit-dialing controls are usually matched to cases on area code (in the United States, the first three digits of the telephone number) and exchange (the three digits following the area code). In the past, area code and prefix were related to residence location and telephone type (land line or mobile service). Thus, if geographic location or participation in mobile telephone plans was likely related to exposure, then the matching should be taken into account in the analysis. More recently, telephone companies in the United States have assigned overlaying area codes and have allowed subscribers to retain their telephone number when they move within the region, so the correspondence between assigned telephone numbers and geographic location has diminished.

Hospital- or Clinic-Based Controls

As noted above, the source population for hospital- or clinic-based case-control studies is not often identifiable, because it represents a group of people who would be treated in a given clinic or hospital if they developed the disease in question. In such situations, a random sample of the general population will not necessarily correspond to a random sample of the source population. If the hospitals or clinics that provide the cases for the study treat only a small proportion of cases in the geographic area, then referral patterns to the hospital or clinic are important to take into account in the sampling of controls. For these studies, a control series comprising patients from the same hospitals or clinics as the cases may provide a less biased estimate of effect than generalpopulation controls (such as those obtained from case neighborhoods or by random-digit dialing). The source population does not correspond to the population of the geographic area, but only to the people who would seek treatment at the hospital or clinic were they to develop the disease under study. Although the latter population may be difficult or impossible to enumerate or even define very clearly, it seems reasonable to expect that other hospital or clinic patients will represent this source population better than general-population controls. The major problem with any nonrandom sampling of controls is the possibility that they are not selected independently of exposure in the source population. Patients who are hospitalized with other diseases, for example, may be unrepresentative of the exposure distribution in the source population, either because exposure is associated with hospitalization, or because the exposure is associated with the other diseases, or both. For example, suppose the study aims to evaluate the relation between tobacco smoking and leukemia using hospitalized cases. If controls are people who are hospitalized with other conditions, many of them will have been hospitalized for conditions associated with smoking. A variety of other cancers, as well as cardiovascular diseases and respiratory diseases, are related to smoking. Thus, a control series of people hospitalized for diseases other than leukemia would include a higher proportion of smokers than would the source population of the leukemia cases.

Limiting the diagnoses for controls to conditions for which there is no prior indication of an association with the exposure improves the control series. For example, in a study of smoking and hospitalized leukemia cases, one could exclude from the control series anyone who was hospitalized with a disease known to be related to smoking. Such an exclusion policy may exclude most of the potential controls, because cardiovascular disease by itself would represent a large proportion of hospitalized patients. Nevertheless, even a few common diagnostic categories should suffice to

find enough control subjects, so that the exclusions will not harm the study by limiting the size of the control series. Indeed, in limiting the scope of eligibility criteria, it is reasonable to exclude categories of potential controls even on the suspicion that a given category might be related to the exposure. If wrong, the cost of the exclusion is that the control series becomes more homogeneous with respect to diagnosis and perhaps a little smaller. But if right, then the exclusion is important to the ultimate validity of the study.

On the other hand, an investigator can rarely be sure that an exposure is not related to a disease or to hospitalization for a specific diagnosis. Consequently, it would be imprudent to use only a single diagnostic category as a source of controls. Using a variety of diagnoses has the advantage of potentially diluting the biasing effects of including a specific diagnostic group that is related to the exposure, and allows examination of the effect of excluding certain diagnoses.

Excluding a diagnostic category from the list of eligibility criteria for identifying controls is intended simply to improve the representativeness of the control series with respect to the source population. Such an exclusion criterion does not imply that there should be exclusions based on disease history (Lubin and Hartge, 1984). For example, in a case-control study of smoking and hospitalized leukemia patients, one might use hospitalized controls but exclude any who are hospitalized because of cardiovascular disease. This exclusion criterion for controls does not imply that leukemia cases who have had cardiovascular disease should be excluded; only if the cardiovascular disease was a cause of the hospitalization should the case be excluded. For controls, the exclusion criterion should apply only to the cause of the hospitalization used to identify the study subject. A person who was hospitalized because of a traumatic injury and who is thus eligible to be a control would not be excluded if he or she had previously been hospitalized for cardiovascular disease. The source population includes people who have had cardiovascular disease, and they should be included in the control series. Excluding such people would lead to an underrepresentation of smoking relative to the source population and produce an upward bias in the effect estimates.

If exposure directly affects hospitalization (for example, if the decision to hospitalize is in part based on exposure history), the resulting bias cannot be remedied without knowing the hospitalization rates, even if the exposure is unrelated to the study disease or the control diseases. This problem was in fact one of the first problems of hospital-based studies to receive detailed analysis (Berkson, 1946), and is often called Berksonian bias; it is discussed further under the topics of selection bias (Chapter 9) and collider bias (Chapter 12).

Other Diseases

In many settings, especially in populations with established disease registries or insurance-claims databases, it may be most convenient to choose controls from people who are diagnosed with other diseases. The considerations needed for valid control selection from other diagnoses parallel those just discussed for hospital controls. It is essential to exclude any diagnoses known or suspected to be related to exposure, and better still to include only diagnoses for which there is some evidence indicating that they are unrelated to exposure. These exclusion and inclusion criteria apply only to the diagnosis that brought the person into the registry or database from which controls are selected. The history of an exposure-related disease should not be a basis for exclusion. If, however, the exposure directly affects the chance of entering the registry or database, the study will be subject to the Berksonian bias mentioned earlier for hospital studies.

Friend Controls

Choosing friends of cases as controls, like using neighborhood controls, is a design that inherently uses individual matching and needs to be evaluated with regard to the advantages and disadvantages of such matching (discussed in Chapter 11).

Aside from the complications of individual matching, there are further concerns stemming from use of friend controls. First, being named as a friend by the case may be related to the exposure status of the potential control (Flanders and Austin, 1986). For example, cases might preferentially name as friends their acquaintances with whom they engage in specific activities that might relate to the exposure. Physical activity, alcoholic beverage consumption, and sun exposure are examples of such exposures. People who are more reclusive may be less likely to be named as friends, so their exposure patterns will be underrepresented among a control series of friends. Exposures more common to extroverted people may become overrepresented among friend controls. This type of

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bias was suspected in a study of insulin-dependent diabetes mellitus in which the parents of cases identified the controls. The cases had fewer friends than controls, had more learning problems, and were more likely to dislike school. Using friend controls could explain these findings (Siemiatycki, 1989).

A second problem is that, unlike other methods of control selection, choosing friends as controls cedes much of the decision making about the choice of control subjects to the cases or their proxies (e.g., parents). The investigator who uses friend controls will usually ask for a list of friends and choose randomly from the list, but for the creation of the list, the investigator is completely dependent on the cases or their proxies. This dependence adds a potential source of bias to the use of friend controls that does not exist for other sources of controls.

A third problem is that using friend controls can introduce a bias that stems from the overlapping nature of friendship groups (Austin et al., 1989; Robins and Pike, 1990). The problem arises because different cases name groups of friends that are not mutually exclusive. As a result, people with many friends become overrepresented in the control series, and any exposures associated with such people become overrepresented as well (see Chapter 11).

In principle, matching categories should form a mutually exclusive and collectively exhaustive partition with respect to all factors, such as neighborhood and age. For example, if matching on age, bias due to overlapping matching groups can arise from *caliper matching*, a term that refers to choosing controls who have a value for the matching factor within a specified range of the case's value. Thus, if the case is 69 years old, one might choose controls who are within 2 years of age 69. Overlap bias can be avoided if one uses nonoverlapping age categories for matching. Thus, if the case is 69 years old, one might choose controls from within the age category 65 to 69 years. In practice, however, bias due to overlapping age and neighborhood categories is probably minor (Robins and Pike, 1990).

Dead Controls

A dead control cannot be a member of the source population for cases, because death precludes the occurrence of any new disease. Suppose, however, that the cases are dead. Does the need for comparability argue in favor of using dead controls? Although certain types of comparability are important, choosing dead controls will misrepresent the exposure distribution in the source population if the exposure causes or prevents death in a substantial proportion of people or if it is associated with an uncontrolled factor that does. If interviews are needed and some cases are dead, it will be necessary to use proxy respondents for the dead cases. To enhance comparability of information while avoiding the problems of taking dead controls, proxy respondents can also be used for those live controls matched to dead cases (Wacholder et al., 1992b). The advantage of comparable information for cases and controls is often overstated, however, as will be addressed later. The main justification for using dead controls is convenience, such as in studies based entirely on deaths (see the discussion of proportional mortality studies below and in Chapter 6).

OTHER CONSIDERATIONS FOR SUBJECT SELECTION

Representativeness

Some textbooks have stressed the need for representativeness in the selection of cases and controls. The advice has been that cases should be representative of all people with the disease and that controls should be representative of the entire nondiseased population. Such advice can be misleading. A case-control study may be restricted to any type of case that may be of interest: female cases, old cases, severely ill cases, cases that died soon after disease onset, mild cases, cases from Philadelphia, cases among factory workers, and so on. In none of these examples would the cases be representative of all people with the disease, yet perfectly valid case-control studies are possible in each one (Cole, 1979). The definition of a case can be quite specific as long as it has a sound rationale. The main concern is clear delineation of the population that gave rise to the cases.

Ordinarily, controls should represent the source population for cases (within categories of stratification variables), rather than the entire nondiseased population. The latter may differ vastly from the source population for the cases by age, race, sex (e.g., if the cases come from a Veterans Administration hospital), socioeconomic status, occupation, and so on—including the exposure of interest.

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One of the reasons for emphasizing the similarities rather than the differences between cohort and case-control studies is that numerous principles apply to both types of study but are more evident in the context of cohort studies. In particular, many principles relating to subject selection apply identically to both types of study. For example, it is widely appreciated that cohort studies can be based on special cohorts rather than on the general population. It follows that case-control studies can be conducted by sampling cases and controls from within those special cohorts. The resulting controls should represent the distribution of exposure across those cohorts, rather than the general population, reflecting the more general rule that controls should represent the source population of the cases in the study, not the general population.

Comparability of Information Accuracy

Some authors have recommended that information obtained about cases and controls should be of comparable or equal accuracy, to ensure nondifferentiality (equal distribution) of measurement errors (Miettinen, 1985a; Wacholder et al., 1992a; MacMahon and Trichopoulos, 1996). The rationale for this principle is the notion that nondifferential measurement error biases the observed association toward the null, and so will not generate a spurious association, and that bias in studies with nondifferential error is more predictable than in studies with differential error.

The comparability-of-information (equal-accuracy) principle is often used to guide selection of controls and collection of data. For example, it is the basis for using proxy respondents instead of direct interviews for living controls whenever case information is obtained from proxy respondents. In most settings, however, the arguments for the principle are logically inadequate. One problem, discussed at length in Chapter 9, is that nondifferentiality of exposure measurement error is far from sufficient to guarantee that bias will be toward the null. Such guarantees require that the exposure errors also be *independent* of errors in other variables, including disease and confounders (Chavance et al., 1992; Kristensen, 1992), a condition that is not always plausible (Lash and Fink, 2003b). For example, it seems likely that people who conceal heavy alcohol use will also tend to understate other socially disapproved behaviors such as heavy smoking, illicit drug use, and so on.

Another problem is that the efforts to ensure equal accuracy of exposure information will also tend to produce equal accuracy of information on other variables. The direction of overall bias produced by the resulting nondifferential errors in confounders and effect modifiers can be larger than the bias produced by differential error from unequal accuracy of exposure information from cases and controls (Greenland, 1980; Brenner, 1993; Marshall and Hastrup, 1996; Marshall et al., 1999; Fewell et al., 2007). In addition, unless the exposure is binary, even independent nondifferential error in exposure measurement is not guaranteed to produce bias toward the null (Dosemeci et al., 1990). Finally, even when the bias produced by forcing equal measurement accuracy is toward the null, there is no guarantee that the bias is less than the bias that would have resulted from using a measurement with differential error (Greenland and Robins, 1985a; Drews and Greenland, 1990; Wacholder et al., 1992a). For example, in a study that used proxy respondents for cases, use of proxy respondents for the controls might lead to greater bias than use of direct interviews with controls, even if the latter results in greater accuracy of control measurements.

The comparability-of-information (equal accuracy) principle is therefore applicable only under very limited conditions. In particular, it would seem to be useful only when confounders and effect modifiers are measured with negligible error and when measurement error is reduced by using equally accurate sources of information. Otherwise, the bias from forcing cases and controls to have equal measurement accuracy may be as unpredictable as the effect of not doing so and risking differential error (unequal accuracy).

Number of Control Groups

Situations arise in which the investigator may face a choice between two or more possible control groups. Usually, there will be advantages for one group that are missing in the other, and vice versa. Consider, for example, a case-control study based on a hospitalized series of cases. Because they are hospitalized, hospital controls would be unrepresentative of the source population to the extent that exposure is related to hospitalization for the control conditions. Neighborhood controls would not suffer this problem, but might be unrepresentative of persons who would go to the hospital if they had the study disease. So which control group is better? In such situations, some

have argued that more than one control group should be used, in an attempt to address the biases from each group (Ibrahim and Spitzer, 1979). For example, Gutensohn et al. (1975), in a case-control study of Hodgkin disease, used a control group of spouses to control for environmental influences during adult life but also used a control group of siblings to control for childhood environment and sex. Both control groups are attempting to represent the same source population of cases, but have different vulnerabilities to selection biases and match on different potential confounders.

Use of multiple control groups may involve considerable labor, so is more the exception than the rule in case-control research. Often, one available control source is superior to all practical alternatives. In such settings, effort should not be wasted on collecting controls from sources likely to be biased. Interpretation of the results will also be more complicated unless the different control groups yield similar results. If the two groups produced different results, one would face the problem of explaining the differences and attempting to infer which estimate was more valid. Logically, then, the value of using more than one control group is quite limited. The control groups can and should be compared, but a lack of difference between the groups shows only that both groups incorporate similar net bias. A difference shows only that at least one is biased, but does not indicate which is best or which is worst. Only external information could help evaluate the likely extent of bias in the estimates from different control groups, and that same external information might have favored selection of only one of the control groups at the design stage of the study.

Timing of Classification and Diagnosis

Chapter 7 discussed at length some basic principles for classifying persons, cases, and person-time units in cohort studies according to exposure status. The same principles apply to cases and controls in case-control studies. If the controls are intended to represent person-time (rather than persons) in the source population, one should apply principles for classifying person-time to the classification of controls. In particular, principles of person-time classification lead to the rule that controls should be classified by their exposure status as of their selection time. Exposures accrued after that time should be ignored. The rule necessitates that information (such as exposure history) be obtained in a manner that allows one to ignore exposures accrued after the selection time. In a similar manner, cases should be classified as of time of diagnosis or disease onset, accounting for any built-in lag periods or induction-period hypotheses. Determining the time of diagnosis or disease onset can involve all the problems and ambiguities discussed in the previous chapter for cohort studies and needs to be resolved by study protocol before classifications can be made.

As an example, consider a study of alcohol use and laryngeal cancer that also examined smoking as a confounder and possible effect modifier, used interviewer-administered questionnaires to collect data, and used neighborhood controls. To examine the effect of alcohol and smoking while assuming a 1-year lag period (a 1-year minimum induction time), the questionnaire would have to allow determination of drinking and smoking habits up to 1 year before diagnosis (for cases) or selection (for controls).

Selection time need not refer to the investigator's identification of the control, but instead may refer to an event analogous to the occurrence time for the case. For example, the selection time for controls who are cases of other diseases can be taken as time of diagnosis for that disease; the selection time of hospital controls might be taken as time of hospitalization. For other types of controls, there may be no such natural event analogous to the case diagnosis time, and the actual time of selection will have to be used.

In most studies, selection time will precede the time data are gathered. For example, in interview-based studies, controls may be identified and then a delay of weeks or months may occur before the interview is conducted. To avoid complicating the interview questions, this distinction is often ignored and controls are questioned about habits in periods dating back from the interview.

VARIANTS OF THE CASE-CONTROL DESIGN

NESTED CASE-CONTROL STUDIES

Epidemiologists sometimes refer to specific case-control studies as *nested* case-control studies when the population within which the study is conducted is a fully enumerated cohort, which allows formal

random sampling of cases and controls to be carried out. The term is usually used in reference to a case-control study conducted within a cohort study, in which further information (perhaps from expensive tests) is obtained on most or all cases, but for economy is obtained from only a fraction of the remaining cohort members (the controls). Nonetheless, many population-based case-control studies can be thought of as nested within an enumerated source population. For example, when there is a population-based disease registry and a census enumeration of the population served by the registry, it may be possible to use the census data to sample controls randomly.

CASE-COHORT STUDIES

The *case-cohort study* is a case-control study in which the source population is a cohort and (within sampling or matching strata) every person in this cohort has an equal chance of being included in the study as a control, regardless of how much time that person has contributed to the person-time experience of the cohort or whether the person developed the study disease. This design is a logical way to conduct a case-control study when the effect measure of interest is the ratio of incidence proportions rather than a rate ratio, as is common in perinatal studies. The average risk (or incidence proportion) of falling ill during a specified period may be written

$$R_1 = \frac{A_1}{N_1}$$

for the exposed subcohort and

$$R_0 = \frac{A_0}{N_0}$$

for the unexposed subcohort, where R_1 and R_0 are the incidence proportions among the exposed and unexposed, respectively, and N_1 and N_0 are the initial sizes of the exposed and unexposed subcohorts. (This discussion applies equally well to exposure variables with several levels, but for simplicity we will consider only a dichotomous exposure.) Controls should be selected such that the exposure distribution among them will estimate without bias the exposure distribution in the source population. In a case-cohort study, the distribution we wish to estimate is among the $N_1 + N_0$ cohort members, not among their person-time experience (Thomas, 1972; Kupper et al., 1975; Miettinen, 1982a).

The objective is to select controls from the source cohort such that the ratio of the number of exposed controls (B_1) to the number of exposed cohort members (N_1) is the same as the ratio of the number of unexposed controls (B_0) to the number of unexposed cohort members (N_0) , apart from sampling error:

$$\frac{B_1}{N_1} = \frac{B_0}{N_0}$$

Here, B_1/N_1 and B_0/N_0 are the control sampling fractions (the number of controls selected per cohort member). Apart from random error, these sampling fractions will be equal if controls have been selected independently of exposure.

We can use the frequencies of exposed and unexposed controls as substitutes for the actual denominators of the incidence proportions to obtain "pseudo-risks":

Pseudo-risk₁ =
$$\frac{A_1}{B_1}$$

and

$$Pseudo-risk_0 = \frac{A_0}{B_0}$$

These pseudo-risks have no epidemiologic interpretation by themselves. Suppose, however, that the control sampling fractions are equal to the same fraction, f. Then, apart from sampling error, B_1/f should equal N_1 , the size of the exposed subcohort; and B_0/f should equal N_0 , the size of the unexposed subcohort: $B_1/f = B_1/(B_1/N_1) = N_1$ and $B_0/f = B_0/(B_0/N_0) = N_0$. Thus, to get the

incidence proportions, we need only multiply each pseudo-risk by the common sampling fraction, f. If this fraction is not known, we can still compare the sizes of the pseudo-risks by division:

$$\frac{\text{Pseudo-risk}_1}{\text{Pseudo-risk}_0} = \frac{A_1/B_1}{A_0/B_0} = \frac{A_1/[(B_1/N_1)N_1]}{A_0/[(B_0/N_0)N_0]} = \frac{A_1/fN_1}{A_0/fN_0} = \frac{A_1/N_1}{A_0/fN_0}$$

In other words, the ratio of pseudo-risks is an estimate of the ratio of incidence proportions (risk ratio) in the source cohort if control sampling is independent of exposure. Thus, using a case-cohort design, one can estimate the risk ratio in a cohort without obtaining information on every cohort member.

Thus far, we have implicitly assumed that there is no loss to follow-up or competing risks in the underlying cohort. If there are such problems, it is still possible to estimate risk or rate ratios from a case-cohort study, provided that we have data on the time spent at risk by the sampled subjects or we use certain sampling modifications (Flanders et al., 1990). These procedures require the usual assumptions for rate-ratio estimation in cohort studies, namely, that loss-to-follow-up and competing risks either are not associated with exposure or are not associated with disease risk

An advantage of the case-cohort design is that it facilitates conduct of a set of case-control studies from a single cohort, all of which use the same control group. As a sample from the cohort at enrollment, the control group can be compared with any number of case groups. If matched controls are selected from people at risk at the time a case occurs (as in risk-set sampling, which is described later), the control series must be tailored to a specific group of cases. If common outcomes are to be studied and one wishes to use a single control group for each outcome, another sampling scheme must be used. The case-cohort approach is a good choice in such a situation.

Case-cohort designs have other advantages as well as disadvantages relative to alternative case-control designs (Wacholder, 1991). One disadvantage is that, because of the overlap of membership in the case and control groups (controls who are selected may also develop disease and enter the study as cases), one will need to select more controls in a case-cohort study than in an ordinary case-control study with the same number of cases, if one is to achieve the same amount of statistical precision. Extra controls are needed because the statistical precision of a study is strongly determined by the numbers of distinct cases and noncases. Thus, if 20% of the source cohort members will become cases, and all cases will be included in the study, one will have to select 1.25 times as many controls as cases in a case-cohort study to ensure that there will be as many controls who never become cases in the study. On average, only 80% of the controls in such a situation will remain noncases; the other 20% will become cases. Of course, if the disease is uncommon, the number of extra controls needed for a case-cohort study will be small.

DENSITY CASE-CONTROL STUDIES

Earlier, we described how case-control odds ratios will estimate rate ratios if the control series is selected so that the ratio of the person-time denominators T_1/T_0 is validly estimated by the ratio of exposed to unexposed controls B_1/B_0 . That is, to estimate rate ratios, controls should be selected so that the exposure distribution among them is, apart from random error, the same as it is among the person-time in the source population or within strata of the source population. Such control selection is called *density sampling* because it provides for estimation of relations among incidence rates, which have been called *incidence densities*.

If a subject's exposure may vary over time, then a case's exposure history is evaluated up to the time the disease occurred. A control's exposure history is evaluated up to an analogous index time, usually taken as the time of sampling; exposure after the time of selection must be ignored. This rule helps ensure that the number of exposed and unexposed controls will be in proportion to the amount of exposed and unexposed person-time in the source population.

The time during which a subject is eligible to be a control should be the time in which that person is also eligible to become a case, if the disease should occur. Thus, a person in whom the disease has already developed or who has died is no longer eligible to be selected as a control. This rule corresponds to the treatment of subjects in cohort studies. Every case that is tallied in the numerator of a cohort study contributes to the denominator of the rate until the time that the person

becomes a case, when the contribution to the denominator ceases. One way to implement this rule is to choose controls from the set of people in the source population who are at risk of becoming a case at the time that the case is diagnosed. This set is sometimes referred to as the *risk set* for the case, and this type of control sampling is sometimes called *risk-set sampling*. Controls sampled in this manner are matched to the case with respect to sampling time; thus, if time is related to exposure, the resulting data should be analyzed as matched data (Greenland and Thomas, 1982). It is also possible to conduct unmatched density sampling using probability sampling methods if one knows the time interval at risk for each population member. One then selects a control by sampling members with probability proportional to time at risk and then randomly samples a time to measure exposure within the interval at risk.

As mentioned earlier, a person selected as a control who remains in the study population at risk after selection should remain eligible to be selected once again as a control. Thus, although it is unlikely in typical studies, the same person may appear in the control group two or more times. Note, however, that including the same person at different times does not necessarily lead to exposure (or confounder) information being repeated, because this information may change with time. For example, in a case-control study of an acute epidemic of intestinal illness, one might ask about food ingested within the previous day or days. If a contaminated food item was a cause of the illness for some cases, then the exposure status of a case or control chosen 5 days into the study might well differ from what it would have been 2 days into the study.

CUMULATIVE ("EPIDEMIC") CASE-CONTROL STUDIES

In some research settings, case-control studies may address a risk that ends before subject selection begins. For example, a case-control study of an epidemic of diarrheal illness after a social gathering may begin after all the potential cases have occurred (because the maximum induction time has elapsed). In such a situation, an investigator might select controls from that portion of the population that remains after eliminating the accumulated cases; that is, one selects controls from among noncases (those who remain noncases at the end of the epidemic follow-up).

Suppose that the source population is a cohort and that a fraction f of both exposed and unexposed noncases is selected to be controls. Then the ratio of pseudo-frequencies will be

$$\frac{A_1/B_1}{A_0/B_0} = \frac{A_1/f(N_1 - A_1)}{A_0/f(N_0 - A_0)} = \frac{A_1/(N_1 - A_1)}{A_0/(N_0 - A_0)}$$

which is the incidence odds ratio for the cohort. This ratio will provide a reasonable approximation to the rate ratio, provided that the proportions falling ill in each exposure group during the risk period are low, that is, less than about 20%, and that the prevalence of exposure remains reasonably steady during the study period (see Chapter 4). If the investigator prefers to estimate the risk ratio rather than the incidence rate ratio, the study odds ratio can still be used (Cornfield, 1951), but the accuracy of this approximation is only about half as good as that of the odds-ratio approximation to the rate ratio (Greenland, 1987a). The use of this approximation in the cumulative design is the primary basis for the mistaken teaching that a rare-disease assumption is needed to estimate effects from case-control studies.

Before the 1970s, the standard conceptualization of case-control studies involved the cumulative design, in which controls are selected from noncases at the end of a follow-up period. As discussed by numerous authors (Sheehe, 1962; Miettinen, 1976a; Greenland and Thomas, 1982), density designs and case-cohort designs have several advantages outside of the acute epidemic setting, including potentially much less sensitivity to bias from exposure-related loss-to-follow-up.

CASE-ONLY, CASE-SPECULAR, AND CASE-CROSSOVER STUDIES

There are a number of situations in which cases are the only subjects used to estimate or test hypotheses about effects. For example, it is sometimes possible to employ theoretical considerations to construct a prior distribution of exposure in the source population and use this distribution in place of an observed control series. Such situations arise naturally in genetic studies, in which basic

laws of inheritance may be combined with certain assumptions to derive a population or parental-specific distribution of genotypes (Self et al., 1991). It is also possible to study certain aspects of joint effects (interactions) of genetic and environmental factors without using control subjects (Khoury and Flanders, 1996); see Chapter 28 for details.

When the exposure under study is defined by proximity to an environmental source (e.g., a power line), it may be possible to construct a *specular* (hypothetical) control for each case by conducting a "thought experiment." Either the case or the exposure source is imaginarily moved to another location that would be equally likely were there no exposure effect; the case exposure level under this hypothetical configuration is then treated as the (matched) "control" exposure for the case (Zaffanella et al., 1998). When the specular control arises by examining the exposure experience of the case outside of the time in which exposure could be related to disease occurrence, the result is called a *case-crossover study*.

The classic *crossover* study is a type of experiment in which two (or more) treatments are compared, as in any experimental study. In a crossover study, however, each subject receives both treatments, with one following the other. Preferably, the order in which the two treatments are applied is randomly chosen for each subject. Enough time should be allocated between the two administrations so that the effect of each treatment can be measured and can subside before the other treatment is given. A persistent effect of the first intervention is called a *carryover effect*. A crossover study is only valid to study treatments for which effects occur within a short induction period and do not persist, i.e., carryover effects must be absent, so that the effect of the second intervention is not intermingled with the effect of the first.

The *case-crossover* study is a case-control analog of the crossover study (Maclure, 1991). For each case, one or more predisease or postdisease time periods are selected as matched "control" periods for the case. The exposure status of the case at the time of the disease onset is compared with the distribution of exposure status for that same person in the control periods. Such a comparison depends on the assumption that neither exposure nor confounders are changing over time in a systematic way.

Only a limited set of research topics are amenable to the case-crossover design. The exposure must vary over time within individuals rather than stay constant. Eye color or blood type, for example, could not be studied with a case-crossover design because both are constant. If the exposure does not vary within a person, then there is no basis for comparing exposed and unexposed time periods of risk within the person. Like the crossover study, the exposure must also have a short induction time and a transient effect; otherwise, exposures in the distant past could be the cause of a recent disease onset (a carryover effect).

Maclure (1991) used the case-crossover design to study the effect of sexual activity on incident myocardial infarction. This topic is well suited to a case-crossover design because the exposure is intermittent and is presumed to have a short induction period for the hypothesized effect. Any increase in risk for a myocardial infarction from sexual activity is presumed to be confined to a short time following the activity. A myocardial infarction is an outcome that is well suited to this type of study because it is thought to be triggered by events close in time. Other possible causes of a myocardial infarction that might be studied by a case-crossover study would be caffeine consumption, alcohol consumption, carbon monoxide exposure, drug exposures, and heavy physical exertion (Mittleman et al., 1993), all of which occur intermittently.

Each case and its control in a case-crossover study is automatically matched on all characteristics (e.g., sex and birth date) that do not change within individuals. Matched analysis of case-crossover data controls for all such fixed confounders, whether or not they are measured. Subject to special assumptions, control for measured time-varying confounders may be possible using modeling methods for matched data (see Chapter 21). It is also possible to adjust case-crossover estimates for bias due to time trends in exposure through use of longitudinal data from a nondiseased control group (case-time controls) (Suissa, 1995). Nonetheless, these trend adjustments themselves depend on additional no-confounding assumptions and may introduce bias if those assumptions are not met (Greenland, 1996b).

There are many possible variants of the case-crossover design, depending on how control time periods are selected. These variants offer trade-offs among potential for bias, inefficiency, and difficulty of analysis; see Lumley and Levy (2000), Vines and Farrington (2001), Navidi and Weinhandl (2002), and Janes et al. (2004, 2005) for further discussion.

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TWO-STAGE SAMPLING

Another variant of the case-control study uses two-stage or two-phase sampling (Walker, 1982a; White, 1982b). In this type of study, the control series comprises a relatively large number of people (possibly everyone in the source population), from whom exposure information or perhaps some limited amount of information on other relevant variables is obtained. Then, for only a subsample of the controls, more detailed information is obtained on exposure or on other study variables that may need to be controlled in the analysis. More detailed information may also be limited to a subsample of cases. This two-stage approach is useful when it is relatively inexpensive to obtain the exposure information (e.g., by telephone interview), but the covariate information is more expensive to obtain (say, by laboratory analysis). It is also useful when exposure information already has been collected on the entire population (e.g., job histories for an occupational cohort), but covariate information is needed (e.g., genotype). This situation arises in cohort studies when more information is required than was gathered at baseline. As will be discussed in Chapter 15, this type of study requires special analytic methods to take full advantage of the information collected at both stages.

PROPORTIONAL MORTALITY STUDIES

Proportional mortality studies were discussed in Chapter 6, where the point was made that the validity of such studies can be improved if they are designed and analyzed as case-control studies. The cases are deaths occurring within the source population. Controls are not selected directly from the source population, which consists of living people, but are taken from other deaths within the source population. This control series is acceptable if the exposure distribution within this group is similar to that of the source population. Consequently, the control series should be restricted to categories of death that are not related to the exposure. See Chapter 6 for a more detailed discussion.

CASE-CONTROL STUDIES WITH PREVALENT CASES

Case-control studies are sometimes based on prevalent cases rather than incident cases. When it is impractical to include only incident cases, it may still be possible to select existing cases of illness at a point in time. If the prevalence odds ratio in the population is equal to the incidence-rate ratio, then the odds ratio from a case-control study based on prevalent cases can unbiasedly estimate the rate ratio. As noted in Chapter 4, however, the conditions required for the prevalence odds ratio to equal the rate ratio are very strong, and a simple general relation does not exist for age-specific ratios. If exposure is associated with duration of illness or migration out of the prevalence pool, then a case-control study based on prevalent cases cannot by itself distinguish exposure effects on disease incidence from the exposure association with disease duration or migration, unless the strengths of the latter associations are known. If the size of the exposed or the unexposed population changes with time or there is migration into the prevalence pool, the prevalence odds ratio may be further removed from the rate ratio. Consequently, it is always preferable to select incident rather than prevalent cases when studying disease etiology.

As discussed in Chapter 3, prevalent cases are usually drawn in studies of congenital malformations. In such studies, cases ascertained at birth are prevalent because they have survived with the malformation from the time of its occurrence until birth. It would be etiologically more useful to ascertain all incident cases, including affected abortuses that do not survive until birth. Many of these, however, do not survive until ascertainment is feasible, and thus it is virtually inevitable that case-control studies of congenital malformations are based on prevalent cases. In this example, the source population comprises all conceptuses, and miscarriage and induced abortion represent emigration before the ascertainment date. Although an exposure will not affect duration of a malformation, it may very well affect risks of miscarriage and abortion.

Other situations in which prevalent cases are commonly used are studies of chronic conditions with ill-defined onset times and limited effects on mortality, such as obesity, Parkinson's disease, and multiple sclerosis, and studies of health services utilization.

Exhibit 21

Ovarian Cancer and Talc

A Case-Control Study

DANIEL W. CRAMER, MD,*†; WILLIAM R. WELCH, MD,§ ROBERT E. SCULLY, MD,[§]
AND CAROL A. WOJCIECHOWSKI, RN;

Opportunities for genital exposure to talc were assessed in 215 white females with epithelial ovarian cancers and in 215 control women from the general population matched by age, race, and residence. Ninety-two (42.8%) cases regularly used talc either as a dusting powder on the perineum or on sanitary napkins compared with 61 (28.4%) controls. Adjusted for parity and menopausal status, this difference yielded a relative risk of 1.92 (P < 0.003) for ovarian cancer associated with these practices. Women who had regularly engaged in both practices had an adjusted relative risk of 3.28 (P < 0.001) compared to women with neither exposure. This provides some support for an association between talc and ovarian cancer hypothesized because of the similarity of ovarian cancer to mesotheliomas and the chemical relation of talc to asbestos, a known cause of mesotheliomas. The authors also investigated opportunities for potential talc exposure from rubber products such as condoms or diaphragms or from pelvic surgery. No significant differences were noted between cases and controls in these exposures, although the intensity of talc exposure from these sources was likely affected by variables not assessed in this study. Cancer 50:372-376, 1982.

THE POSSIBILITY that ovarian cancer may be caused by exposure to certain hydrous magnesium silicates such as talc and asbestos has been raised by several researchers. The lack of epidemiologic studies regarding this hypothesis prompted us to investigate talc exposure in a case-control study of ovarian cancer.

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Methods

The cases studied were women with ovarian cancer, diagnosed between November 1978 and September 1981 and identified through the pathology logs or tumor boards of twelve participating hospitals in the Greater Boston area. The study was restricted to English-speaking residents of Massachusetts ranging in age from 18 to 80 years. During the study period, 297 eligible cases were identified. Physicians denied permission to contact their patients in 13 instances. Fourteen patients declined to participate, and 14 other patients had died or moved before they could be contacted.

For each of the 256 interviewed cases, slides of the surgical specimens were reviewed by two authors (W.R.W. or R.E.S). Eighteen cases were excluded as nonovarian primaries. Each ovarian tumor was classified according to the Histological Classification of Ovarian Tumors of the World Health Organization.⁴ The present analysis was restricted to 215 white women with epithelial cancers, including 39 with tumors of borderline malignancy and their matched controls.

Control cases were identified through the Massachusetts Town Books, annual publications that list residents by name, age, and address. Controls were selected randomly from those women who matched cases by precinct of residence, race, and age within two years. Additionally, it was required that a subject be excluded

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as a control if she had had a bilateral salpingo-oophorectomy, but subjects were not excluded because of prior hysterectomy or other types of pelvic operations. Women who had had pelvic operations were generally confident in their knowledge of whether their ovaries had been removed, but the nature of the operations could not be verified by hospital records in each instance. Women whose statements could not be verified were included or excluded on the basis of their recollection of the surgery. The 215 controls in this study were eventually obtained from a total of 475 potential controls identified through the Town Books. Fifty-six (12%) of the total could not be reached because they had moved, died, or had disconnected or unlisted phones. Twenty-nine (6%) of the total were ineligible because of a history of bilateral salpingo-oophorectomy, while 20 (4%) were of the wrong age or race or did not speak English. Of the total potential controls, 155 (33%) refused to participate. If the 215 cases are characterized as to ease of matching, 121 (56%) cases were matched with no refusals, 58 (27%) were matched after one refusal, and 36 (17%) were matched only after two or more refusals.

Interviews were conducted personally to assess a number of factors from the menstrual and reproductive history, medical and family history, and environmental exposures. This report will deal only with the results of several questions related to potential or definite talc exposure by way of contraceptive practices, operations, or perineal hygiene. Subjects were stratified by potential confounders described below, and adjusted relative risks associated with these exposures were calculated by the Mantel-Haenszel procedure as adapted by Rothman and Boice. To accommodate other confounders as well as the matched design in the data collection, logistic analysis for matched data as described by Breslow et al. was also employed.

Results

The average age (and standard error of the mean, SEM) for cases was 53.2 (1.0) years and for controls,

TABLE 1. Characteristics of Cases and Controls

		ises = 215)	Controls (Total = 215)		
Characteristic	No.	%	No.	%	
Educational level					
(completed				•••	
college)	48	22.3	49	22.8	
Religion (Roman					
Catholic)	126	58.6	128	59.5	
Marital status					
(never married)	46	21.4	24	11.2	
Nulliparous	78	36.3	39	18.1	
Menopausal status					
(postmenopausal*)	137	63.7	129	60.0	

^{*} Postmenopausal at time of diagnosis for cases or for interview for controls.

53.5 (1.0) years. Table 1 shows other characteristics of subjects. Controls were comparable to cases in educational level and religion. Cases and controls differed significantly in marital status and parity with parity being the more important discriminator between them. Sixty-four percent of the cases were postmenopausal at the time of diagnosis, whereas 60% of controls were postmenopausal. Of these, 15 cases and 20 controls had had an artificial menopause. Parity and menopausal status were considered important potential confounders in this analysis and were adjusted for as described above.

Relative risks associated with potential talc exposure from contamination on rubber products are explored in Table 2. Although surgical gloves of recent vintage are dusted with starch, talc contamination may still be found.⁷ Thus, a history of pelvic operations (appendectomy, cesarean section, hysterectomy, and other operations on internal genital organs other than bilateral salpingo-oophorectomy) was determined in cases and controls. Excluding operations associated with the diagnosis or treatment of the ovarian cancer among the cases, no excess in the occurrence of pelvic operations was noted. The greatest opportunity for talc exposure from surgery occurred before 1950, when talc was the

TABLE 2. Relative Risks (RR) for Common Epithelial Ovarian Cancers Associated with Potential Talc Exposure from Contamination on Rubber Products

		Cases	Controls				
Exposure	Total	No. (%) with exposure	Total	No. (%) with exposure	Crude RR	Adjusted RR*	95% Confidence limits
Pelvic surgery Pelvic surgery (prior	215	78 (36.3)	215	75 (34.9)	1.06	1.17	(0.76-1.79)
to 1950)	215	51 (23.7)	215	48 (22.3)	1.08	1.12	(0.69-1.82)
Use of condoms†	169	19 (11.2)	191	30 (15.7)	0.68	0.77	(0.41-1.44)
Use of diaphragm [†]	169	37 (21.9)	191	35 (18.3)	1.24	1.19	(0.69-2.05)

^{*} Adjusted for parity (nulliparous, parous) and menopausal status (pre- and postmenopausal).

[†] Restricted to subjects who had ever been married.

TABLE 3. Relative Risks (RR) Associated with Using Talc for Storage Among Diaphragm Users* by Duration of Use of Diaphragm

		Cases		Controls			
Duration of diaphragm use	Total	No. (%) who used talc on diaphragm	Total	No. (%) who used talc on diaphragm	Crude RR	Adjusted RR†	95% Confidence limits
Total diaphragm use							
less than five years Total diaphragm use	13	6 (46.2)	21	8 (38.1)	1.39	1.82	(0.42-8.00)
five or more years	27	16 (59.3)	19	11 (57.9)	1.06	1.23	(0.36-4.17)
All users	40	22 (55.0)	40	19 (47.5)	1.35	1.56	(0.62-3.88)

Includes all women who used diaphragm regardless of marital status.

predominantly used dusting powder for surgical gloves. However, no significant excess of pelvic operations prior to 1950 was observed for cases.

The patients (cases) who, at sometime, had been married, chose condoms less frequently and diaphragms more frequently for contraception than the control group, but neither difference was statistically significant. Condom use is not necessarily associated with talc exposure. Not all brands of condoms are dusted with talc, and lubricants could affect the shedding of talc from the condom. Unfortunately, details on specific brands of condoms were not obtained. Similarly, talc exposure is not a necessary consequence of diaphragm use. We inquired specifically about the practice of dusting the diaphragm with talc for storage after use (Table 3). Among all subjects who had used a diaphragm, there was no significant excess of cases who regularly stored their diaphragm using talc, nor was any greater risk associated with this practice observed among women who had used the diaphragm for longer durations. Before the risk from this exposure can be adequately assessed, greater detail is needed including frequency of use and whether the powder was washed off prior to use. Furthermore, contraceptive jellies used with the diaphragm could affect the transport of talc in the genital tract.

Hygienic practices involving talc were also studied. Specifically, we inquired whether women had regularly used talc as a dusting powder on the perineum or regularly dusted sanitary napkins with talc (Table 4). Ninety-two (42.8%) of the cases had talc exposure by either or both of these routes compared with 61 (28.4%) of the controls. The adjusted relative risk was 1.92 (P < 0.003) with 95% confidence limits of 1.27-2.89 compared to subjects who had neither exposure. Sixty (27.9%) cases and 48 (22.3%) controls had either used tale for dusting or on napkins but not both. This difference yielded an adjusted relative risk of 1.55, which was of borderline significance (P = 0.06). The greatest risk occurred in women who had both exposures (use on the perineum and on napkins) compared to women who had neither exposure. Thirty-two (14.9%) of cases were in this category compared with 13 (6.0%) controls, for an adjusted relative risk of 3.28 (P < .001) and 95% confidence limits of 1.68-6.42. The histologic characteristics of tumors developing in women with perineal exposure to tale did not differ significantly from those in women without perineal exposure to talc (Table 5). In addition, the proportion of cases with tumors of borderline malignancy was identical among those with and without perineal exposure to talc. Twenty-two (18%) of 123 cases without the exposure had tumors of bor-

TABLE 4. Relative Risks (RR) for Common Epithelial Ovarian Cancers Associated with Talc Exposure in Perineal Hygiene

				Types of perineal expos	ure
	No perineal exposure	Any perineal exposure	As dusting powder but not on napkins	On napkins but not as dusting powder	Both on napkins and as dusting powder
Cases					
(Total = 215)	123 (57.2%)	92 (42.8%)	43 (20.0%)	17 (7.9%)	32 (14.9%)
Controls		• •			
(Total = 215)	154 (71.6%)	61 (28.4%)	34 (15.8%)	14 (6.5%)	13 (6.0%)
Crude rr	1	1.89	1.58	1.52	3.08
Adjusted RR*	_	1.92	1.5	55	3.28
95% confidence limits		(1.27-2.89)	(0.98 -	2.47)	(1.68-6.42)

^{*} Adjusted for parity and menopausal status.

[†] Adjusted for parity and menopausal status.

No. 2

derline malignancy compared to 17 (18%) of 92 with the talc exposure.

Discussion

The argument linking talc and ovarian cancer includes four elements: the chemical relationship between talc and asbestos, asbestos as a cause of pleural and peritoneal mesotheliomas, the possible relation between epithelial ovarian cancers and mesotheliomas, and the ability of talc to enter the pelvic cavity. The mineral talc is a specific hydrous magnesium silicate chemically related to several asbestos group minerals and occurring in nature with them. Generic "talc" is seldom pure and may be contaminated with asbestos, particularly in powders formulated prior to 1976.

Epidemiologic studies have clearly linked lung cancer and pleural and peritoneal mesotheliomas with asbestos exposure. 10 An excess of similar pulmonary lesions has been reported in talc workers and seems to be correlated with the amount of asbestos contamination in the talc deposits worked. 11 Graham and Graham were able to induce ovarian neoplasms in guinea pigs with asbestos and suggested that ovarian cancer could be related to asbestos exposure, noting the similarity between mesotheliomas and ovarian cancers. Parmley and Woodruff¹² further emphasized this similarity and popularized the pelvic contamination theory, which proposed that environmental carcinogens might enter the pelvic cavity via the genital tract. Years earlier it had been observed that inert carbon particles placed in the vagina immediately prior to hysterectomy could be recovered from the fallopian tubes. 13 Although greeted with skepticism, the finding of talc particles embedded in normal and abnormal ovaries suggests that talc is a substance that can enter the pelvic cavity via the vagina.²

Although no consensus concerning the risks of talc has emerged from letters, editorial and articles, 3,14-16 participants in the discussion have agreed upon the need for epidemiologic studies of ovarian cancer and talc exposure. In this case-control study of ovarian cancer of the epithelial variety, we investigated several sources of potential talc exposure. Among these, the only significant finding was an association between ovarian cancer and hygienic practices involving the use of talc on the perineum. It is especially notable that women who regularly had both dusted their perineum with talc and had used it on sanitary napkins had more than a three-fold increase in risk compared to women with neither exposure. Several potential biases must be considered in interpreting this association.

The observation by Wynder et al. 17 that menstrual characteristics may differ between women with ovarian cancer and controls might suggest that such differences may confound the association between perineal use of

TABLE 5. Characteristics of Ovarian Cancer in Women with and without Perineal Exposure to Talc

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	No perineal use of talc	Any perineal use of talc
	No. (%)	No. (%)
Serous	66 (53.7)	45 (48.9)
Mucinous	16 (13.0)	14 (15.2)
Endometrioid and clear cell Other and	32 (26.0)	24 (26.1)
undifferentiated	9 (7.3)	9 (9.8)
Total	123 (100)	92 (100)

talc and ovarian cancer. We found that menstrual characteristics of cases and controls were virtually identical in this study. Fifty-three (24.7%) cases complained of moderate or severe dysmenorrhea compared to 56 (26.0%) controls. Twenty-five (11.6%) cases complained of irregular periods compared to 32 (14.9%) controls. The average numbers (and SEM) of days of flow and cycle length were, respectively, 4.9 (0.1) and 28.9 (0.3) days for cases and 4.9 (0.1) and 29.6 (0.3) days for controls.

Since entry of talc into the pelvic cavity is prevented by hysterectomy or tubal ligation, it might also be argued that the inclusion of subjects with pelvic surgery in the analysis may obviate any association between talc and ovarian cancer. It should be noted that such surgery generally occurred near the end of reproductive life for both cases and controls, probably after most significant talc exposure had already occurred. The exclusion of such subjects from the analysis did not substantially alter the observed associations. For example, the adjusted relative risk for the use of talc both on the perineum and sanitary napkins was $2.79 \ (P < 0.003)$ in the group without pelvic surgery compared to 3.28 observed for the entire group.

In terms of other confounders, the association persisted after adjustment for menopausal status and parity. We also applied multivariate logistic regression for paired observations. The maximum likelihood estimate of relative risk associated with any perineal use of talc was 1.61 (P = 0.03) with 95% confidence limits of 1.04-2.49 after simultaneous adjustment for religion, marital status, educational level, ponderal index, age at menarche, exact parity, oral contraceptive or menopausal hormone use, and smoking.

Our sample of cases represents more than 50% of ovarian cancer cases diagnosed in Boston residents in the study period. Therefore, it is difficult to conceive of a plausible bias in the selection of cases that would yield this excess use of talc. There is reason for concern that the high refusal rate among the controls may have introduced a selection bias among the controls. But,

when we restricted the analysis to the 121 cases who were matched without a control refusal, we again found a significant association between talc use and ovarian cancer. For women who had used talc both in dusting and on the perineum we found an adjusted relative risk of $2.44 \ (P < 0.05)$. Interviewer bias is also unlikely to explain the association. Of the 18 women who were initially interviewed as ovarian cancer cases but later excluded as having metastatic tumors to the ovary, only one (5.6%) had both perineal and napkin exposure as compared with 15% in cases and 6% in controls.

Experimental data which might bear on the carcinogenicity of talc come primarily from models using pleural implantation of various minerals in rats. ¹⁸ These data suggest that carcinogenicity is dependent primarily upon the shape of the particles with long thin fibers such as those occurring in crocidolite asbestos being most carcinogenic. Talc consists primarily of plates but may contain fibers, although voluntary guidelines to limit the content of asbestisform fibers in consumer talcums were proposed by the cosmetics industry in 1976. ¹⁹

If talc is involved in the etiology of ovarian cancer, it is not clear whether this derives from the asbestos content of talc or from the uniqueness of the ovary which might make it susceptible to carcinogenesis from both talc and other particulates. With ovulation entrapment of the surface epithelium of the ovary into the ovarian stroma occurs. If present, talc or other particulates might be incorporated into these inclusion cysts. Apparently implantation of foreign bodies into the lumens of epithelial lined organs provides a favorable environment for carcinogenesis.20 Alternatively, talc might serve to stimulate entrapment of the surface epithelium and act in the same way that "incessant ovulation" has been proposed as an etiologic factor for ovarian cancer.21 Given the histologic and clinical diversity of ovarian cancer, talc exposure is unlikely to be the only cause. Undoubtedly, reproductive experiences such as pregnancies and, perhaps, oral contraceptive use play a role in its etiology. 21-23 The possibility that talc exposure interacts with these variables deserves further investigation.

It is hoped that this report will stimulate further study of talc exposure in relation to ovarian cancer. Animal studies would be helpful to determine whether and under what circumstances ovarian tumors may be induced by various talc preparations. Epidemiologic studies should focus on opportunities for excessive vaginal contamination with talc such as when it is repeatedly used in perineal dusting powders or sprays and in or on tampons, sanitary napkins, or other products intended for

intravaginal use. More precise details on the exact nature and frequency of the exposure and the amount and specific brand of powder used are essential. Opportunities for talc exposure are widespread and pervasive, ²⁴ but that should not discourage epidemiologists from studying this potentially important exposure in relation to ovarian cancer.

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Exhibit 22

diabetologists and in major medical centers where funduscopic examination is done routinely and competently. However, in the office of the primary care physicians, where most diabetics in this country receive much of their care, annual examination of the fundi through dilated pupils regrettably is performed infrequently if at all. Given that circumstance, an abnormal tourniquet test result demands a competent funduscopic examination to rule out proliferative retinopathy, often by referral to an ophthalmologist. I wish to emphasize that I am not advocating that the tourniquet test replace regular funduscopic examination.

If Drs Aaby and Zegarra have a cost-effective strategy to ensure adequate annual examination of the 11 million diabetics in the United States "by a physician who can recognize early proliferative diabetic retinopathy," I would happily endorse it and discard the tourniquet test; until then, the tourniquet test will identify nine of every ten patients with diabetic retinopathy who need to be referred to such a physician. Many of these patients' conditions are currently undiagnosed until loss of vision occurs.

Decrease in capillary fragility with improved diabetic control noted in several patients was not meant to imply regression of diabetic retinopathy. Histological study, however, may confirm that the tourniquet test does accurately reflect the progression or regression of diabetic dermal microangiopathy. At present, the vascular or platelet abnormality causing capillary fragility in diabetes is unknown. I am currently involved in a study correlating the tourniquet test with fluorescein retinal angiography in those patients who do not have identifiable diabetic retinopathy on ophthalmoscopic examination.

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Talc and Ovarian Cancer

To the Editor.—Cramer and co-workers' recently reported observing an association between talc use and risk of ovarian cancer. We therefore examined data on talc use that two of us (L.M. and L.P.L.) had collected as part of a case-control interview study

	Cases	Controls	Estimated Relative Risk	95% Confidence Interval
No talc mentioned	62	61	1.0	
Any talc mentioned	67	100	0.7	0.4-1.1
No diaphragm used	92	118	1.0	
Diaphragm used, no talc	14	11	1.6	0.7-3.7
Diaphragm, with talc	25	41	0.8	0.4-1.4
No body talc	77	84	1.0	
Some body talc "All over"	54 37	78 57	0.8 0.7	0.5-1.2 0.4-1.2
Genital*	7	3	2.5	0.7-10.0
Legs only	1	0		
Not genital	6	8	0.8	0.3-2.5
Haknaum whara	•	10	0.0	0110

^{*}On genitals, sanitary napkins, or underwear.

of epithelial ovarian cancer conducted from 1974 to 1977 in the Washington. DC, area.2 The cases were 197 women with pathologically confirmed priepithelial ovarian cancers treated in participating hospitals. The controls were 197 women treated at the same hospitals for conditions other than gynecologic, psychiatric, or malignant diseases or pregnancy. The controls were frequency matched to the cases on age, race, and hospital. The interviewers asked questions about reproductive and sexual history, medical history, drug use, and other exposures. Questions about talc use were added to the questionnaire after the study began, so 135 cases and 171 controls were asked about talc exposure.

The reported talc use among cases and controls is given in the Table. We estimated the relative risk to talc users as 0.7 (95% confidence interval [CI]=0.4 to 1.1). The estimate was unaffected by adjustment for race, age, and gravidity. Neither women who used talc on their diaphragms nor those who used it as body powder seemed to be at excess risk. Women who used talc as a body powder were asked how they used it. Among the ten who specifically mentioned use on sanitary napkins, underwear, or the genital area, the relative risk was estimated as 2.5, but the small number of exposed women yielded an unreliable estimate (95% CI=0.7 to 10.0).

Our data thus indicate no overall association between talc use and risk of ovarian cancer. Although a small group of women who specifically reported genital use of body talcum powders showed an excess relative risk, use of talc on a diaphragm, which would be the closest exposure to the ovaries, did not seem to elevate risk

Chance, bias in selection or observation, or confounding may have influenced these estimates. One important potential bias to consider in this and Cramer's study is a difference between cases and controls in recollecting or reporting talcum powder use, especially in the genital area. Talc exposure was not a major focus of this study, and few data are available to assess the likelihood of recall bias. Such a bias could stem from cases' heightened awareness or from the fact that controls were interviewed in the hospital while most cases were interviewed at home. On the other hand, the questions about talc use were rather simple and unambiguous. Also, we noted that cases and controls were equally likely to report douching. Since reporting of use of douches might be subject to the same recall biases as talc use, this observation suggests that little recall bias operated. Another possible interpretation of our findings of no apparent effect of using talc on the diaphragm but some effect of perineal use of powder is that talc itself does not increase risk of ovarian cancer but that patients with ovarian cancer have or perceive a greater need for using body powder in the genital area, for reasons related either to the biology of the disease or to life-style. We agree with Cramer and co-workers that other epidemiologic data will be useful.

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Letters

Exhibit 23

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PERSONAL AND ENVIRONMENTAL CHARACTERISTICS RELATED TO EPITHELIAL OVARIAN CANCER

II. EXPOSURES TO TALCUM POWDER, TOBACCO, ALCOHOL, AND COFFEE

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Whittemore, A. S. (Stanford U. School of Medicine, Dept. of Health Research and Policy, Stanford, CA 94305-5092), M. L. Wu, R. S. Paffenbarger, Jr., D. L. Sarles, J. B. Kampert, S. Grosser, D. L. Jung, S. Ballon, and M. Hendrickson. Personal and environmental characteristics related to epithelial ovarian cancer. II. Exposures to talcum powder, tobacco, alcohol, and coffee. *Am J Epidemiol* 1988;128:1228-40.

Vaginal exposures to talc and other particulates may play an etiologic role in epithelial ovarian cancer. Surgical sterilization may protect against ovarian cancer by blocking entry of such particulates into the peritoneal cavity. The authors assessed histories of talcum powder use, tubal sterilization, and hysterectomy with ovarian conservation in 188 women in the San Francisco Bay Area with epithelial ovarian cancers diagnosed in 1983-1985 and in 539 control women. To investigate the roles of blood-borne environmental exposures on ovarian cancer risk, they assessed lifetime consumption of coffee, tobacco, and alcohol in these women. Of the 539 controls, 280 were hospitalized women without overt cancer, and 259 were chosen from the general population by random digit telephone dialing. Ninety-seven (52%) of the cancer patients habitually used talcum powder on the perineum, compared with 247 (46%) of the controls. Adjusted for parity, the relative risk (RR) = 1.40, p = 0.06. There were no statistically significant trends with increasing frequency or duration of talc use, and patients did not differ from controls in use of talc on sanitary pads and/or contraceptive diaphragms. Fewer ovarian cancer patients (7%) than controls (13%) reported prior fallopian tube ligation (RR, adjusted for parity, = 0.56, p = 0.06), and fewer patients (20%) than controls (28%) reported prior hysterectomy (RR = 0.66, p = 0.05). The protective effect of hysterectomy was confined to those who underwent this surgery 10 or more years prior to interview and to those who had not undergone prior tubal sterilization. Consumption of cigarettes and alcohol did not differ between cases and controls. By contrast, 11 (6%) cases never regularly consumed coffee, compared with 31 (11%) hospital controls and 26 (10%) population controls (RR, adjusted for smoking, = 2.2, p = 0.03, for the comparison using all controls). Overall, ovarian cancer risk among women who had drunk coffee for more than 40 years was 3.4 times that of women who had never regularly consumed coffee (p < 0.01). However, the data exhibited no clear trends in risk with increasing consumption. Although risk ratios relating duration of coffee drinking to ovarian cancer were unaffected by adjustment for several characteristics, further study is needed to exclude potential confounding by other unmeasured characteristics.

alcohol drinking; coffee; environmental exposure; hysterectomy; ovarian neoplasms; talc; tobacco; sterilization, tubal

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Several investigators have hypothesized a carcinogenic role for exposures of the epithelium to environmental ovarian agents that enter the pelvic cavity through the vaginal canal (1-7). Attention has focused on hydrous magnesium silicates such as talc and asbestos because of the similarity between epithelial ovarian cancers and mesotheliomas, which are caused by exposure to asbestos. The hypothesis predicts that talcum powder use on the perineum, on sanitary napkins, and on contraceptive devices increases ovarian cancer risk. It also predicts that tubal sterilization and hysterectomy without bilateral oophorectomy protect against the disease by preventing environmental carcinogens from contacting the ovarian epithelium.

There are few data regarding these predicted consequences of the hypothesis. Cramer et al. (8) reported that ovarian cancer patients were significantly more likely than nonhospitalized control women to use talcum powder on the perineum or on sanitary napkins. However, Hartge et al. (9) found no statistically significant differences in prior talc use between cases and a series of hospital controls. A cohort study (10) of women who had undergone tubal ligation noted four ovarian cancers versus 1.45 expected, after 22,000 person-years of follow-up (p = 0.06). The four published case-control studies that have examined the effects of hysterectomy without bilateral oophorectomy found cases to have a lower prevalence of hysterectomy than controls, indicating that hysterectomy is associated with decreased risk of ovarian cancer (11-14). Weiss and Harlow (15) suggested that this association may be due to screening for malignant or premalignant ovarian conditions at hysterectomy by physicians

who do not routinely remove the ovaries. According to this hypothesis, women who pass such screening would have reduced subsequent ovarian cancer risk when compared with women who were not subjected to hysterectomy.

Data relating ovarian cancer to consumption of coffee, tobacco, and alcohol also are sparse and conflicting. One case-control study has shown a statistically significant association between coffee consumption and increased risk of epithelial ovarian cancer (16). This study compared cases with hospitalized control women, whose current coffee consumption may not represent that of women in the general population. Four other studies using hospitalized controls (17-20) and one using nonhospitalized controls (21) found weak, nonsignificant positive associations between risk of this disease and amount of usual coffee consumption at interview. It is important to determine to what extent these conflicting findings may be due to differences in recent coffee consumption between hospitalized and population-based control groups or to other sources of bias.

Cigarette smoking has been associated with increased ovarian cancer risk in one prospective study (22) but was unassociated with it in several case-control studies (16, 17, 21). Indeed, the case-control studies have found small (nonsignificant) reductions in risk among smokers. Generally, such studies have found no relation between alcohol consumption and ovarian cancer, although a recent large study found a reduction in risk associated with heavy drinking (23).

We present the results of a case-control study of histologically verified epithelial ovarian carcinoma in which cases' prior histories of talc use, tubal ligation, hysterectomy without bilateral oophorectomy, and consumption of coffee, tobacco, and alcohol were compared with those of women from the general population, as well with those of hospitalized control women. All subjects reported lifetime habits of talc use, coffee drinking, cigarette smoking, and alcohol consumption. Sum-

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mary measures of lifetime exposures are evaluated in relation to ovarian cancer risk.

MATERIALS AND METHODS

Study subjects

Cases were residents of northern California aged 18 to 74 years who were diagnosed during the period January 1983 to December 1985 at one of the seven hospitals in Santa Clara County or at the University of California, San Francisco, Medical Center. The present report is restricted to 188 women with primary epithelial ovarian cancer.

Two groups of control women were selected. The first group consisted of women who were hospitalized in one of the hospitals to which cases were admitted. The second group was selected from the general population using random digit dialing telephone contacts. Both groups of women were matched to cases on age (within five-year intervals), race (white, black, oriental), and additional criteria described in the accompanying paper (24). A total of 188 ovarian cancer patients, 280 hospital controls, and 259 population-based controls participated.

Exposure data and statistical analysis

Study subjects participated in structured interviews in their homes conducted by trained interviewers to assess menstrual and reproductive history, medical and family history, and environmental exposures. Subjects were asked whether they had ever used talcum powder on the perineum, on sanitary pads, or on diaphragms. Subjects who responded affirmatively to any of these questions were asked about frequency and duration of use. Subjects also were asked whether they had ever drunk more than 10 cups of coffee in any one year. Subjects who responded affirmatively reported the ages when coffee drinking started and stopped, the total number of years of coffee drinking, and the number of cups usually consumed per day or per week either currently or prior to stopping. Similar questions were asked

about cigarette smoking, provided that the subject had smoked at least 100 cigarettes during her life, and about consumption of alcoholic beverages, provided that she had ever consumed more than 10 such beverages in any one year.

Eligibility criteria, participation rates, and details of the statistical analysis are provided in the accompanying paper (24). Odds ratios are called relative risks, and all p values are two-tailed.

RESULTS

Characteristics of the cases are compared with those of the two control groups in table 1. Population controls were somewhat younger, better educated, and more likely to be premenopausal than were cases and hospital controls. Furthermore, cases were less likely to have used oral contraceptives and had an earlier age at menarche and

TABLE 1

Characteristics of study participants, San Francisco

Bay Area, 1983–1985

	Cases	Cor	ntrols
Characteristic	(n = 188) (%)	Hospital (n = 280) (%)	Population (n = 259) (%)
Age (years)			
<40	10	10	15
40-49	. 30	29	29
50-59	26	28	27
60+	35	33	29
Race			
White	95	97	94
Education (years)			
>12	59	59	67
No. of term pregnan-	•		
cies*			
0	21	17	10
1-3	60	59	67
4+	19	24	23
Age (years) at men- arche			
12 or less	48	44	46
Menopausal status			
Premenopausal	34	32	41
Natural menopause	45	33	38
Surgical menopause	22	. 35	2 1
Oral contraceptives			
Ever used	46	50	58

^{* 20} or more weeks gestation.

OVARIAN CANCER AND ENVIRONMENTAL EXPOSURES

fewer term pregnancies than either control group. The latter findings are reported in detail in the companion paper (24).

Relative risks associated with talc use, tubal ligation, and hysterectomy were similar when cases were compared with hospital controls and with population controls. Therefore, for these variables, we report results only for cases versus the combined group of all controls.

Talc use

A greater proportion of cases (52 per cent) than controls (46 per cent) reported prior use of talcum powder on the perineum (relative risk (RR) = 1.40, p = 0.06). However, there was little difference between cases and controls in use of talc on sanitary pads and diaphragms, with relative risks of $0.93 \ (p = 0.76) \ \text{and} \ 0.95 \ (p = 0.86), \ \text{respec}$ tively. Table 2 shows the distributions of cases and controls and relative risks for talc use directly on the perineum, on sanitary pads, and on contraceptive diaphragms, singly and in combination. The table provides no evidence of elevated risk associated with more than one form of talc use. None of the women in the study reported prior occupational exposures to talc or asbestos fibers.

We next examined whether risk increased with increased duration or frequency of use of talcum powder on the perineum. Since tubal ligation and hysterectomy prevent contact between the ovarian epithelium and exogenous agents in the vaginal canal, we excluded any perineal talc use after the date of tubal ligation or hysterectomy in calculating duration of use. As seen in table 3, 55 per cent of cases versus 59 per cent of controls reported such use for less than one year. The risk for talc use between one and nine years, relative to that among users of shorter duration, was 1.60 (p = 0.05). However, an increasing doseresponse pattern was not apparent, with risk among long-term users of 10 or more years only 1.11 times that of the nonusers or users of less than one year (p = 0.61). According to the logistic model fit to the data, the overall increase in risk for any 10year increase in duration of use was 1.01 (p = 0.56).

Table 3

Ovarian cancer risk by length of talcum powder use on the perineum,* San Francisco Bay Area, 1983–1985

Years of	Са	ses	Con	trols	Relative	95% confidence	
talc use*	n	%	n	- 710 LT		interval	
None	103	55	320	59	1.00		
1-9	34	18	72	13	1.60	1.00-2.57	
10+	50	27	147	27	1.11	0.74 - 1.65	
Unknown	1	1	0	0			
Total	188	100	539	100			

^{*} Prior to tubal ligation or hysterectomy.

TABLE 2

Ovarian cancer risk by type of talcum powder use, San Francisco Bay Area, 1983–1985

	Са	ses	Controls		Relative	95% confidence
Type of talc use	n	%	n	%	risk*	interval
None	·75	40	230	43	1.00	
Perineum only)	22	12	55	10	1.45	0.81 - 2.60
Sanitary pads only	5	3	28	5	0.62	0.21 - 1.80
Diaphragm only	9	5	19	. 4	1.50	0.63-3.58
Any two of perineum, pads, and			-			
diaphragm	• 67	- 36	168	31	1.36	0.91 - 2.04
All three of perineum, pads, and						
diaphragm	1	1	9	2	0.35	0.04 - 2.94
Incomplete data	9	5	30	6		
Total	188	100	539	100		

^{*} Adjusted for parity and oral contraceptive use.

[†] Adjusted for parity.

The relation between ovarian cancer risk and usual frequency of talc use on the perineum is shown in table 4. Women who used talc an average of one to 20 times per month were not at significantly altered risk from those who used it less frequently (RR = 1.27, p = 0.29). Those who customarily used talc on the perineum 20 or more times per month were at 1.45 times the risk of women in the lowest use category (p = 0.09). The overall increase in risk associated with 30 applications per month was 1.30 (p = 0.19).

Tubal ligation and hysterectomy

To investigate further the hypothesis of a role for vaginal exposure to environmental carcinogens in the etiology of ovarian cancer, we examined the effect of tubal ligation and hysterectomy on risk for the disease. Seven per cent of cases and 13 per cent of controls reported a history of tubal ligation (RR = 0.53, p = 0.05). Relative risks for tubal ligation were less than one among nulliparous, uniparous, and multiparous women, indicating that the protective effect of such surgery on ovarian cancer risk cannot be explained by confounding due to its greater prevalence among parous women who are at reduced risk of the disease. The overall reduction in risk associated with tubal ligation, adjusted for parity, was 0.56 (p = 0.07).

Cases with tubal ligation tended to undergo this surgery at younger ages (mean age (± standard error) = 31.9 years (±0.5)) than did controls (34.2 years (±0.1)). This difference does not support the hypothesis that early tubal ligation confers greater protection to the ovaries by early termination of exposure from the vaginal canal. Relative to women without this surgery, the risk for women with tubal ligation within 10 years of interview was 0.35 (95 per cent confidence interval (CI) 0.12–1.02), while the risk for women who underwent the surgery more than 10 years before interview was 0.69 (95 per cent CI 0.32–1.50).

Table 5 shows that hysterectomized women experienced 0.66 times the risk of those without such surgery (p = 0.05), but it does not show any trend of decreasing protection with time since hysterectomy. Such a trend would be expected if the protective effect of hysterectomy reflected merely the removal of high-risk women from the hysterectomized population via selective oophorectomy as suggested by Weiss and Harlow (15). On the contrary, table 5 shows that protection is limited to women hysterectomized 10 or more years prior to interview. Overall, cases and controls did not differ significantly in the ages at which hysterectomy was performed. The mean age at hysterectomy among cases with such prior surgery was 40.1 years (± 0.3), while the corresponding age for controls was 39.7 years (± 0.1) .

The hypothesis that hysterectomy protects against ovarian cancer by blocking

TABLE 4

Ovarian cancer risk by usual frequency of talcum powder use on the perineum, San Francisco Bay Area,

1983–1985

A - 1: - 4:	Cases		Con	trols	Relative	95%
Applications of talc per month	\overline{n}	n %	\overline{n}	%	risk*	confidence interval
None	97	52	312	58	1.00	•
1-20	41	. 22	114	21	1.27	0.82 - 1.96
20+	44	23	101	19	1.45	0.94-2.22
Unknown	. 6	3	12	2		•
Total	188	100	539	100		•
Overall trend for 30 uses per month					1.30	0.88-1.92

^{*} Adjusted for parity.

exogenous agents' access to the ovaries predicts that such surgery confers no benefit on women whose ovaries are already protected by prior tubal ligation. Table 5 shows relative risks associated with hysterectomy among women with and without prior tubal ligation. As predicted, hysterectomy failed to protect women who had undergone prior

tubal ligation (RR = 2.56, p = 0.45), but it did protect those who had not (RR = 0.57, p = 0.02).

Table 6 shows the effects of perineal talc use separately among women with and without prior tubal ligation or hysterectomy. The highest risk was experienced by talc users without such surgery. The risk in

TABLE 5

Ovarian cancer risk after hysterectomy without bilateral oophorectomy, by time between hysterectomy and interview and by absence or presence of prior tubal ligation, San Francisco Bay Area, 1983–1985

	Cases		Controls		Relative	95% confidence
	n %	п	%	risk	interval	
No hysterectomy	151	80	389	72	1.00	
Hysterectomy	37	20	150*	28	0.66	0.43-1.00
Time (years) between hysterec-						
tomy and interview				_	4.04	0.54 1.00
1-9	1 5	8	42	8	1.01	0.54-1.89
10–19	11	6	66	12	0.47	0.24-0.92
20+	11	6	41	8	0.63	0.31-1.29
No prior tubal ligation						
No hysterectomy	141	81†	333	71†	1.00	
Hysterectomy	33	19	135	29	0.57	0.36-0.90
Prior tubal ligation						
No hysterectomy	10	71‡	56	79‡	1.00	
Hysterectomy	4	29	15	21	2.56	0.23-29.12

^{*} Date of hysterectomy was unknown for one woman.

TABLE 6

Ovarian cancer risk by perineal talc use and by history of surgical sterilization,† San Francisco Bay Area,
1983–1985

Surgical	Surminal	Cas	es	Cont	rols	Relative	95% confidence
Talc use	sterilization†	n	%	π	%	risk‡	interval
No	No	70	37	182	34	1.00	
Yes	No	71	38	151	28	1.33	0.88-2.01
No	Yes	21	11	110	20	0.50*	0.29-0.88
Yes	Yes	26	14	96	18	0.75	0.43-1.29
No	Total	91	48	292	54	1.00	
Yes	Total	97	52	247	46	1.37§	0.97–1.95
Total	No	141 .	75	333	62	1.00	
Total	Yes	47	25	206	38	0.53*-	0.36-0.79

^{*} p < 0.01.

[†] Per cent of cases or controls with no prior tubal ligation.

[‡] Per cent of cases or controls with prior tubal ligation.

[†] Tubal ligation or hysterectomy.

[‡] Adjusted for parity.

[§] Adjusted for parity and surgical sterilization.

Adjusted for parity and talc use.

this group was 1.33 times that of women with neither history of talc use nor history of surgery (p = 0.18). By contrast, risk was lowest among women with a history of tubal ligation or hysterectomy who never regularly applied talc to the perineum (RR = 0.50, p = 0.02).

Table 6 shows that, regardless of talc use, women who underwent either tubal ligation or hysterectomy without bilateral oophorectomy experienced a risk of 0.53 (p = 0.002) compared with women without such surgery.

Cases and controls did not differ significantly in the prevalence of barrier contraceptive use, devices that prevent entry of semen into the peritoneal cavity. Risks for women who had used diaphragms and condoms were 0.81 (p=0.22) and 0.91 (p=0.59), respectively, relative to risk among nonusers. There was no trend in risk with exposure of the ovaries to semen, defined as sexually active time before tubal ligation or hysterectomy, minus duration of use of condoms and diaphragms.

Coffee, tobacco, and alcohol

Table 7 shows the distribution of cases and controls and relative risks by coffee consumption status (ever vs. never). The relative risk for any coffee consumption, adjusted for eigarette smoking, was 2.21 for both control groups combined (p = 0.03). The relative risk was 2.13 (p = 0.06) for cases versus hospital controls and 1.59 (p = 0.24) for cases versus population controls. The corresponding unadjusted relative risks were 2.03 for combined controls, 1.90 for hospital controls, and 1.51 for population controls (not shown).

Table 7 also shows that risk among coffee drinkers increases with increasing duration of coffee consumption. This trend is evident in both the comparison based on hospital controls and the one based on population controls. Overall, smoking-adjusted cancer rates among women who had consumed coffee for more than 40 years were 3.4 times those of women who had never consumed coffee (p < 0.01). Among coffee drinkers, each additional 10 years of coffee drinking conferred an 11 per cent increase in risk, according to the logistic function fit to the data (p = 0.37). These findings could be confounded by age despite the matching within five-year age groups. However, the results were similar when age was added to the regressions as a continuous variable.

Relations between ovarian cancer risk and amount of usual coffee consumption are shown in table 8. The table provides no evidence for a positive trend in risk with

TABLE 7 Ovarian cancer risk by years of coffee consumption, San Francisco Bay Area, 1983–1985

Years of coffee consumption	Cases		Controls				Relative risk†			
	n	%	Hospital		Population		Cases vs.	Cases vs.	Cases vs.	95% confidence
			'n	%	n	%	hospital controls	population controls	all controls	interval‡
None	11	6	31	11	26	10	1.00	1.00	1.00	
Any	177	94	249	89	233	90	2.13	1.59	2.21	1.10-4.41
1-14	18	10	27	10	34	13	1.57	0.65	1,45	0.59-3.57
15-24	32	17	43	15	.36	14	1.81	1.69	2.18	1.00~4.79
25-39	62	33	105	38	98	38	2.36	1.70	2.26	1.06-4.85
40+	65	35	73	26	64	25	3.45*	2.54	3.41*	1.46-7.96
Unspecified	. 0	0	1	0	1	0			0.11	2.10 1.00
Overall trend per 10 years										
among coffee drinkers							1.16	1.14	1.11	0.89 - 1.38

^{*} p < 0.01

[†] Adjusted for smoking (lifelong nonsmoker vs. ever smoker).

[‡] Cases versus all controls.

frequency of coffee drinking, regardless of the control group used for comparison. Frequency was measured as usual number of cups consumed per day prior to disease onset for cases and hospital controls who were current coffee drinkers, and as usual number of cups per day prior to stopping for former coffee drinkers. The test for trend of increasing risk with increasing frequency among those who consumed coffee was not significant (p = 0.91).

Similarly, table 9 shows no trend in risk with total cups of coffee consumed prior to disease onset (cases and hospital controls)

or prior to interview (population controls). We estimated total coffee consumption by multiplying each woman's reported duration of coffee consumption in years by her usual frequency of consumption in cups per day times 365. Among coffee drinkers, the test for trend in risk with increasing total consumption yielded a p value of 0.56.

Relative risks corresponding to the above measures of coffee consumption were unchanged by adjustment for other variables potentially associated with ovarian cancer including educational level, parity, oral contraceptive use, estimated years of ovu-

Table 8

Ovarian cancer risk by usual frequency of coffee consumption,* San Francisco Bay Area, 1983–1985

Cups/day	Cases		Controls					95%		
	n	%	Hospital		Population		Cases vs.	Cases vs.	Cases vs.	confidence
			\overline{n}	%	$\frac{-}{n}$	%	hospital controls	population controls	all controls	interval‡
0	11	6	31	11	26	10	1.00	1.00	1,00	
1	50	27	62	22	58	22	2.21	1.86	2.42	1.15 - 5.09
2-3'	73	39	94	34	98	38	2.13	1.63	2.26	1.09 - 4.66
4+	54	29	93	33	77	30	2.02	1.56	2.07	0.97-4.38
verall trend per cup/ day among coffee										
drinkers							1.01	1.01	1.01	0.93 - 1.08

^{*} Prior to stopping for ex-drinkers, and prior to hospitalization for current drinkers, among cases and hospital controls.

TABLE 9

Ovarian cancer risk by estimated total cups of coffee consumed, San Francisco Bay Area, 1983–1985

Cup-years* of coffee consumption	Cases		Controls					~		
	n	%	Hospital		Population		Cases vs.	Cases vs.	Cases vs.	95% confidence interval‡
			\overline{n}	%	n	%	hospital controls	population controls	all controls	·
0	11	6	31	11	. 26	10	1.00	1.00	1.00	
1-30	41	22	50	18	60	23	2.30	1.54	2.30	1.09 - 4.86
31-60	32	17	46	16	32	12	2.21	2.30	2.64	1.21-5.75
61-90	27	14	38	14	32	12	2.03	1.96	2.46	1.10 - 5.51
90+	77	41	114	41	108	42	2.42	1.60	2.28	1.08 - 4.78
Unknown	0	0	1	0	1	0				
Overall trend per 10 cup- years among coffee										
drinkers		•					1.01	1.01	1.01	0.99 - 1.03

^{*} One cup-year equals 365 cups of coffee.

[†] Adjusted for smoking (lifelong nonsmoker vs. ever smoker).

[‡] Cases versus all controls.

[†] Adjusted for smoking (lifelong nonsmoker vs. ever smoker).

[‡] Cases versus all controls.

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lation, and duration of contraceptive-free marriage.

The risk for cigarette smoking relative to lifelong nonsmoking, adjusted for coffee consumption, was 0.73 (p=0.08) for the comparison based on combined control groups. Corresponding relative risks for the hospital and population comparisons were 0.65 (p=0.04) and 0.84 (p=0.39), respectively. Unadjusted relative risks and confidence intervals were similar. While the odds ratios associated with smoking were less than unity, few of them achieved statistical significance.

Cases did not differ from either control group in the prevalence of prior alcohol consumption. For the comparison based on all controls, the relative risk was 0.74 (p=0.14). Furthermore, there was no evidence of a trend in risk with increasing duration or amount of alcohol consumption. Women who drank heavily (20 or more drinks per week) had a risk 0.66 times that of non-drinkers, but the reduction was not statistically significant (p=0.34). None of these observations were altered by adjustment for cigarette smoking or coffee consumption.

Discussion

Genital exposures to talc and other agents

The rationale for suspecting talc as an ovarian carcinogen derives from its chemical relation to and natural occurrence with asbestos. Asbestos causes pleural and peritoneal mesotheliomas (25), which are histologically similar to epithelial ovarian carcinomas (6). Graham and Graham (2) showed that, in guinea pigs and rabbits, asbestos can induce ovarian epithelial hyperplasia similar to early epithelial tumors in women. Evidence suggesting a role for vaginal exposure to particulates in human ovarian carcinogenesis is twofold. First, Egli et al. (26) demonstrated that nonmotile inert carbon particles deposited in the vagina prior to hysterectomy can be recovered in the fallopian tubes. Second, Henderson and coworkers have found talc

particles embedded in both normal and malignant ovarian tissue (27, 28). While these findings indicate that vaginal exposure to particulates can lead to deposition on the ovaries, they do not implicate such exposure in ovarian carcinogenesis, and data relating directly to this possibility are needed.

In a comparison of epithelial ovarian cancer cases and nonhospitalized controls in Boston, Cramer et al. (8) reported a relative risk of 1.92 (p < 0.003) for epithelial ovarian cancer associated with use of talcum powder on the perineum or on sanitary pads. By contrast, the results of a case-control study in Washington, DC (9) and those of the present study show neither a strong nor a consistent association between genital talcum powder exposure and ovarian cancer. In the present data, regular use of talc on the perineum was associated with only a marginally significant elevation in relative risk. Furthermore, there were no clear differences between cases and controls when other forms of genital talc exposure were considered, either singly or in combination. Although the data show a trend of increasing risk with increasing frequency of perineal exposure, the trend is not statistically significant, and there is no trend with duration of exposure. Thus, while these data do not exonerate talc as an ovarian carcinogen, neither do they provide strong evidence to implicate it.

Several sources of bias must be considered as possible explanations for the lack of strong findings related to talc, including the study's failure to interview all eligible ovarian cancer patients and a completely random sample of controls, as well as the potential pitfalls of combining the two control groups. Another source of bias is confounding by differential talc use among women with characteristics predictive of ovarian cancer. However, such confounding seems unlikely. For example, although Wynder et al. (14) reported that certain menstrual characteristics differ between women with ovarian cancer and controls,

we and others (8, 13) found no significant differences between cases and controls in any of several menstrual characteristics examined, including history of amenorrhea, irregular menstrual cycles, and midcycle pain.

An additional source of bias is random error in reported talc use, which tends to attenuate relative risk estimates. Some error seems likely. Nevertheless, there seems only a small probability that these data contain reporting errors large enough to obscure the twofold increase in risk noted by Cramer et al. (8) for talc use on the perineum and on sanitary pads. Further epidemiologic studies are needed to clarify the role of talc as carcinogen, cocarcinogen, or promoter of epithelial ovarian carcinogenesis.

Indirect evidence in support of an etiologic role for vaginal exposures to some exogenous substances derives from the reduced risk associated here with fallopian tube sterilization and hysterectomy, procedures that block entry to the pelvic area through the reproductive tract. Apart from talc and asbestos, vaginally introduced substances that may initiate or promote ovarian cancer include other particulates, semen, spermicidal foams or creams, and douche solutions. We are unaware of data implicating any of these substances.

The reduced risk associated in these data with prior tubal sterilization is inconsistent with the results of a historical prospective study of 666 women who had undergone tubal ligation (10). These women experienced a slight, marginally significant increase in ovarian cancer risk. However, the study involved only four cases of ovarian cancer.

Women tend to undergo tubal sterilization during the height of their reproductive years (on average, in the early fourth decade of life, for the present data). By contrast, hysterectomy is generally performed at the end of the reproductive years, probably after a large fraction of genital exposures have already occurred. It is therefore

noteworthy that the protective effects of hysterectomy noted here were limited to surgery 10 or more years prior to interview. This finding fails to support the conjecture of Weiss and Harlow (15) that the protection of hysterectomy is an artifact due to selective removal of precancerous ovaries at the time of surgery. If such selection explained the association, one would expect to find, as those authors did, a decrease in the level of protection with increasing years since surgery. However, the present data show just the opposite trend. They also indicate that the benefits of hysterectomy are confined to women without prior tubal sterilization, a finding that supports an etiologic role for genital exposures to the ova-

Other explanations are possible for the protective effects of tubal ligation and hysterectomy, if the effects are not due to chance or bias. For example, these procedures may alter the levels and/or the cyclic variations of estrogen, progesterone, or the gonadotropins. Tubal sterilization has been shown to reduce subsequent serum and urinary estrogen levels, possibly by inducing localized hypertension at the ovary (29, 30). Some data (30, 31) suggest that hysterectomy with ovarian conservation also may reduce estrogen production. Elevated estrogen levels have been linked to breast cancer and could be involved in ovarian carcinogenesis, although there are few data to support this possibility (32, 33). Tubal sterilization and hysterectomy may protect by reducing ovarian estrogen exposure. Alternatively, some forms of tubal sterilization have been associated with subsequent increased frequency of abnormal or anovulatory cycles (34, 35). Since estimated number of ovulations has been associated with increased ovarian cancer risk (36, 37), tubal sterilization may protect by suppressing ovulation.

Coffee, tobacco, and alcohol

The present data provide some support for the hypothesis that coffee drinking in-

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creases risk for epithelial ovarian cancer. Comparison of cases versus the combined group of both hospitalized and population-based controls suggests that current or former coffee drinkers experience double the risk of nondrinkers. The relative risk based on comparison of cases versus only the population-based controls was smaller (RR = 1.59) and did not achieve statistical significance. Nevertheless, its magnitude suggests that coffee may be implicated in increased risk for the disease.

The hypothesis is also supported by the dose-response relation noted between risk and duration of coffee drinking among those who had ever drunk coffee. Compared with risks for nondrinkers, smoking-adjusted risks increased from 1.45 for fewer than 15 years of coffee drinking to 3.41 for 40 or more years of consumption. Trends of increasing risk with increasing years of coffee drinking were evident in both hospital and population-based control comparisons and in both smoking-adjusted and unadjusted analyses.

Yet, no trends were evident with increasing amount of usual coffee consumption in cups per day, or with total lifetime consumption, estimated by multiplying reported years of consumption by reported amount of usual consumption prior to illness or cessation of coffee drinking. Instead, risk remained approximately constant at two to three times that of nondrinkers, regardless of amount consumed. This lack of dose response is consistent with the negative findings of other studies (17-20) for trend in risk with increasing coffee consumption at time of interview. The absence of trend noted here may be due to inaccuracies in reported usual consumption as a measure of average coffee drinking frequency. Such inaccuracies (if similar in magnitude between cases and controls) could mask evidence of a doseresponse relation. The observed patterns of trend with duration of coffee drinking and lack of trend with frequency of consumption and total consumption would be consistent with a causal relation if women tended to report their duration of coffee drinking more accurately than they reported the amount they usually consumed.

The present observation of increased ovarian cancer risk among coffee drinkers could be due to several sources of bias. The first possibility is differences between cases and controls in some measured or unmeasured characteristics that are correlated with coffee drinking. Body size is an unlikely source of such confounding, because cases and controls were similar in several assessments of weight, height, and weight for height, as related to body size both at age 20 and in recent years. Relative risks for coffee consumption were not altered in multivariate analyses with other variables found to be predictive of ovarian cancer. These include parity, oral contraceptive use, and duration of contraceptive-free marriage.

Potential confounding by dietary factors must also be considered. Cramer et al. (21) found a statistically significant trend of increasing risk with increasing consumption of animal fat, after adjusting for body weight and parity. Absence of data on dietary fat consumption in the present study precludes examination of potential confounding by this factor.

Second, the stronger association noted when cases were compared with hospital controls could be explained by reduced coffee consumption among these controls after the onset of subclinical disease manifestations. However, a statistically significant trend in risk with years of coffee drinking was also noted when cases were compared with population controls. Furthermore, the two sets of controls had similar prevalences of prior regular coffee drinking. Therefore, the possibility of selection bias among hospital controls seems unlikely to explain the observations.

Third, cases may have overreported their coffee consumption relative to controls. However, this explanation also seems unlikely, in view of the absence of evidence

for such reporting bias in cases' reports of tobacco and alcohol consumption.

To date, seven case-control studies have examined the relation between coffee and ovarian cancer (16–21, and the present study). Of these, two (the present study and one in Italy (16)) found statistically significant elevations of risk among coffee drinkers, with relative risks ranging from 1.5 to 2.0. The remaining five studies, one in Greece (17) and four in the United States (18–21), found slightly and nonsignificantly elevated risks associated with coffee consumption. These disparities are not easily explained by differences in coffee constituents or in women among the different study areas.

It is difficult to propose biologically plausible causal mechanisms to explain the positive associations, if the associations are not due to bias or chance. Coffee consumption has been shown to increase urinary excretion of catecholamines (38-41), suggesting that coffee increases the activity of the adrenal medulla. Coffee consumption also may increase adrenal production of androstenedione. Since peripheral aromatization of androstenedione to estrone forms the primary source of estrogen in postmenopausal women (41), coffee consumption may alter ovarian cancer risk by increasing estrogen production after the menopause. Such a mechanism is speculative, however, in view of the sparsity of data implicating estrogens in ovarian carcinogenesis (32, 33).

Cigarette smoking was associated nonsignificantly with reduced ovarian cancer risk. This finding agrees with those of other case-control studies (16, 17, 21) but disagrees with an increased ovarian cancer risk found in a prospective study of women who smoke (22). The present data show no relation between ovarian cancer risk and duration of cigarette smoking.

The data also provide no evidence for any relation between alcohol consumption and ovarian cancer risk, which is consistent with results of other studies that have examined this issue (17, 20, 21). One large study (23) found that women who consumed 20 or more drinks per week had half the risk of women who did not drink. We also found reduced risk associated with such heavy drinking, but the association did not achieve statistical significance. The lack of significance may be due to small numbers in the present study; thus, the relation of alcohol consumption to ovarian cancer should be examined in larger series.

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Exhibit 24

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Brief Original Contributions

A CASE-CONTROL STUDY OF BORDERLINE OVARIAN TUMORS: THE INFLUENCE OF PERINEAL EXPOSURE TO TALC

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Harlow, B. L. (Harvard Medical School, Brigham and Women's Hospital, Boston, MA 02115), and N. S. Weiss. A case-centrol study of borderline ovarian tumores: the influence of perinsal exposure to tale. Am J Epidemiol 1989;130:390~4.

The authors interviewed 118 female residents of western Washington State with serous and mucinous borderline ovarian tumors diagnosed between 1980 and 1985 and questioned them on their use of hygienic powders. A sample of 158 control women from the same counties were identified through random digit dialing and were interviewed as well. Neither the perineal application of baby powder nor the perineal application of comstarch was associated with an appreciably altered risk of borderline ovarian tumors. However, women who used deodorizing powders alone or in combination with other tale-containing powders had 2.8 times the risk (95% confidence interval 1.1–11.7) of women who had not had perineal exposure to powder. These results suggest that future studies of ovarian tumors in relation to the application of tale-containing powders should consider ascertaining the specific type(s) of powder used.

overien neoplasms; talc

In light of the marked differences in agespecific incidence and patient survival between borderline and malignant epithelial ovarian tumors (1), we conducted a casecontrol study of borderline ovarian tumors to determine whether etiologic differences between these low-grade tumors and their malignant counterparts exist as well. As part of this study, we sought to investigate the possible etiologic role of perineal exposure to talc.

Interest in talc as a potential ovarian carcinogen has grown from reports of oc-

cupational asbestos exposure and ovarian cancer (2-4). Mineral talc, similar in chemical composition to various asbestos minerals, is the common base for most dusting powders that women may apply to the perineum, sanitary napkins, or diaphragma prior to storage (5). Presently, three epidemiologic studies have examined the association between talc exposure and ovarian cancer (8-8).

MATERIALS AND METHODS

The Seattle-Puget Sound Cancer Surveillance System classifies borderline ovarian tumors according to the World Health Organization International Classification of Diseases for Oncology (ICD-O) (9), Female residents of three urban counties of western Washington State diagnosed as having a serous or mucinous borderline ovarian tumor (ICD-O codes 8,440-8,481) were identified from the files of this population-based cancer reporting system. Included were white women aged 20-79 years whose tumors were diagnosed during the years

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1980-1985. Among those tumors subject to an independent pathology review (73 per cent), 83 of 88 (94 per cent) were confirmed as borderline ovarian tumors. Given the high degree of histologic agreement, we chose to include the additional 33 cases whose tumors had not been reviewed. Through random digit dialing, we identified a control group of white women who were similar to the cases with respect to age and county of residence. Controls who had undergone bilateral cophorectomy were excluded from the analysis. Further details of the study methods are described elsewhere (10).

Reproductive, sexual, and medical histories and information on perineal exposure to talc were obtained during an in-person interview. An open-ended question asked women to specify the type(s), but not the brand name(s), of powder they had used for perineal application after bathing, on sanitary napkins, and for diaphragm storage prior to diagnosis (or a similar date for controls). Affirmative responses were categorized either as one or more of three talc-containing powders (baby powder, deodorizing powder, and other or unspecified talcum or "dusting" powders) or as cornstarch.

We were successful in obtaining interviews from 116 cases (68 per cent of those eligible) and 158 controls (74 per cent of those eligible). A detailed discussion of response rates can be found elsewhere (10). Since previous studies (including ours) have reported an association of ovarian cancer risk in relation to reproductive history and exogenous female hormones, we controlled for age, parity, and the use of oral contraceptives during the analysis, by means of stratification (11).

RESULTS

Women who reported any perineal use of dusting powders—either after bathing, on sanitary napkins, or for diaphragm storage—had an adjusted relative risk of 1.1 for developing a borderline ovarian tumor (95 per cent confidence interval (CI) 0.7-2.1) (table 1). We further examined this association according to both the specific

method of exposure to dusting powders and the type of powder used. The analysis by method of use indicates that a smaller proportion of cases than controls used talccontaining powder or cornstarch for diaphragm storage. The risk associated with the use of talc-containing powders or cornstarch after bathing was 1.2 (95 per cent CI 0.6-2.6). Women who reported any use of talc-containing powder or cornstarch on sanitary napkins had a risk about double (relative risk (RR) = 2.2, 95 per cent CI 0.8-19.8) that of women who reported no talc use. This risk was the same for women who reported applying powder both after bathing and to sanitary napkins. No increase in risk was present among shortand long-term diaphragm users, the risk was not modified by the use of cornstarch versus other talc-containing powders, and there was no variation in risk with increasing number of days of use (not shown).

When we compared cases and controls by the type of powder used, there was no excess risk of borderline tumors among women who applied cornatarch, baby powder, or unspecified talcum powder alone or in combination to the perineum. However, women who applied deodorizing powders with or without baby powder (only baby powder was reported as a second powder in women who used deodorizing powders) had nearly three times the risk of developing a borderline ovarian tumor compared with women who reported no perineal use of powder (RR = 2.8, 95 per cent CI 1.1-11.7).

When we examined the type of powder used according to the method of application, the excess risk due to the use of deodorizing powders was present regardless of whether it was applied after bathing or to sanitary napkins. No subjects reported any use of deodorizing powders for diaphragm storage.

DISCUSSION

Our results of perineal exposure to talc no association among women who applied talcum powder to diaphragms, but a modest increase in risk among women who applied

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TABLE 1

Perineal use of talc-containing powder and cornstarch among women with borderline ovarian tumors and their matched controls, by method of use and by type of powder used, western Washington State, 1980–1985

	Cases (n = 116)	Controls (n = 158)	Crude RR*	Adjusted RR†	98% CI*
No perineal exposure to powder	87	94	1.0\$		
Any perineal exposure to powder	49	84	1.1	1.1	0.7-2.1
Method of use					
Diaphragm storage only	8	21	0.6	0.5	0.2 - 1.4
Disphragm storage only or with other methods	11	27	0.6	0.5	0.2-1.3
After bathing only	24	30	1.1	1.2	0.6-2.6
After bathing only or with other methods	34	37	1.3	1,3	0.8 - 2.7
Sanitary napkins only	7	4	2.5	2,2	0.8-19.8
Sanitary napkins only or with other methods	14	10	2.0	1.9	0.9-6.9
After bathing and on sanitary napkins	7	4	2.5	2.2	0.9-19.A
Type of powder used					
Cornstarch only (no combined use)	4	7	8.0	0.8	0.2 - 3.8
Baby powder only	18	31	0.8	0.8	0.4 - 1.9
Baby powder only or combined use	22	34	0.9	0.9	0.5 - 2.0
Tale, unspecified (no combined use)	13	19	1.0	1.0	0.4 - 2.4
Deodorizing powder only	10	4	3.5	3.5	1.2-28.7
Deodorizing powder only or combined use	14	7	2.8	2.8	1.1-11.7
Method and type of powder used					
Any powder use after buthing					
Any use of deodorizing powder	10	å	2.8	3.1	0.8-10.9
No use of deodorizing powder	24	32	1.1	1.1	0.5 - 2.4
Any powder use on sanitary napkins					
Any use of deodorizing powder	8	4	2.8	2.6	0.9=22.4
No use of deodorizing powder	в	6	1.4	1.5	0. 4-6 .5

^{*} RR, relative risk; CI, confidence interval.

talc-containing powders to the perineum or to sanitary napkins—are consistent with those previously reported in studies of malignant ovarian tumors. Cramer et al. (6) observed a 50 per cent excess risk among women who used dusting powders or who applied talc-containing powders to sanitary napkins, and a relative risk of 3.3 among women who applied both. No association was found with use of talcum powder for diaphragm atorage. Hartge et al. (7) also found no excess risk among users of talc for diaphragm atorage, but they did report an association with perineal application

(seven cases, three controls; RR = 2.5, 95 per cent CI 0.7-10.0). Whittemore et al. (8) reported a 40 per cent excess in risk of ovarian cancer associated with perineal exposure only and a modest increase in risk with increasing numbers of applications per month.

An association between tale use and ovarian neoplasms seems biologically plausible, since particulates contaminating the vaginal area may migrate into the pelvic cavity and since particles of tale have been observed within ovarian tissue (12-15). It is also conceivable that the excess risk as-

[†] Adjusted for age (20-39, 40-59, or 60-79 years), parity (nulliparous or parous), and use of oral contraceptives (ever or never).

[‡] Reference group.

sociated with application of tale to the perineum and to sunitary napkins that was seen in the three prior studies, none of which inquired about the type of powder, could have been due to a strong association restricted to the use of deodorizing powders. The lack of an increased risk among women who used talc-containing powder on diaphragms (both in our study and in the previous studies) supports this hypothesis, since deodorizing powder was infrequently used for diaphragm storage. Furthermore, differential asbestos contamination among different types of cosmetic talcum powders cannot be ruled out. Until 1975, USmanufactured cosmetic talcum powders were required to contain at least 90 per cent mineral tale, but until 1968, some products marked as cosmetic talcum powders did not conform to these guidelines (16, 17). In 1976, a study of 21 consumer talcum powders labeled as baby powders, facial powders, or body powders obtained from retail stores in New York City between 1971 and 1975 reported that 10 contained concentrations of asbestiform tremolite and anthophyllite ranging from 0.2 per cent to 14 per cent (4).

Although it is difficult to explain the lack of association among women who used baby powder exclusively, according to the product labels baby powder is reported to contain only tale and no other minerals or deodorizing substances. The product labels from deodorizing powders, body powders, and perfumed dusting powders, on the other hand, indicate that they contain deodorizing substances and a variety of other free and bonded silicas (potentially high in asbestiform fibers (18)) in addition to tale.

We suggest caution when interpreting the results of this study. The elevated risk among women who specifically used decodorizing powders could have been due to chance or applicable only to borderline, not malignant, ovarian tumors. We believe the latter possibility to be unlikely, since the risk associated with the use of any talcontaining powder was similar to that re-

ported in previous studies of women with malignant ovarian tumors. In addition, because of refusals and other reasons for non-participation, we were unable to include approximately 30 per cent of potentially eligible cases and controls. Since nonparticipants were similar to participants with respect to certain characteristics such as age and county of residence, we have no reason to believe that there was any dissimilarity in their use of talc-containing powders.

Given the clues provided by this study regarding the possible importance of deodorizing powders, it would be advisable for future studies to elicit information on the brand names of talc-containing powders and the timing and duration of use of each type of talc-containing powder. Although these data need replication, they raise the possibility that the risk of ovarian tumors in women who apply deodorizing powder to the perineum may not relate to talc per se but rather to asbestos contamination and/or a substance or substances used specifically for deodorization.

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